

URGENT Medical Device Notification

InterPulse®

Attn: Material Manager, OR Director, Risk Manager

Reference Number: RA2026-4390714

September XX 2026



The purpose of this letter is to inform you that the InterPulse systems possess DEHP in Excess of 0.1% w/w.

Products Affected

Catalog Number	Product Description	GTIN	Lot Numbers
0210-010-000	Bone Cleaning Tip	04546540144164	See Appendix A
0210-010-100	Coaxial Bone Cleaning Tip with Soft Shield	04546540861177	
0210-014-100	Coaxial High Flow Tip with Soft Shield	04546540861252	
0210-018-000	Fan Spray Tip	04546540144195	
0210-014-000	High Flow Tip	04546540144188	
0210-110-100	InterPulse Handpiece Set with Coaxial Bone Cleaning Tip & Suction Tube	04546540861641	
0210-114-100	InterPulse Handpiece Set with Coaxial High Flow Tip & Suction Tube	04546540861764	
0210-158-000	InterPulse Handpiece Set with Coaxial Multi-Orifice Tip & Suction Tube	07613327351002	
0210-012-000	Soft Tissue Tip	04546540144171	See Appendix B
0210-110-000	InterPulse Handpiece Set with Bone Cleaning Tip & Suction Tube	04546540683830	
0210-114-000	InterPulse Handpiece Set with High Flow Tip & Suction Tube	04546540673565	See Appendix C
0210-112-000	InterPulse Handpiece Set with Soft Tissue Tip & Suction Tube	04546540144232	See Appendix D
0210-210-000	InterPulse Handpiece Set with Bone Cleaning Tip	07613327003918	
0203-030-000	Dual Irrigation Adaptor	04546540184399	
0210-118-100	InterPulse Handpiece Set with Coaxial Fan Spray Tip & Suction Tube	04546540861795	
0210-118-200	InterPulse Handpiece Set with Retractable Coaxial Fan Spray Tip & Suction Tube	04546540861818	
0210-118-000	InterPulse Handpiece Set with Fan Spray Tip & Suction Tube	04546540144256	
0207-066-000	Soft Cone Splash Shield 12/Box	04546540184740	

Product Description

The Stryker InterPulse System consists of handpieces, irrigation and suction tips, splash shields and rechargeable battery pack. The irrigation handpieces have a dual speed setting and offer suction and irrigation in one unit. These handpieces have removable splash shields that cover the wound during irrigation, a trigger lock, high/low pressure tips for bone cleaning in surgical procedures or soft tissue applications and femoral canal brushes.

Product Issue & Risk

Product labeling does not alert the user that InterPulse® contains di(2-ethylhexyl) phthalate (DEHP) above the 0.1% w/w concentration as required by regulations. Three components of InterPulse® contain DEHP in medical-grade flexible PVC materials. The Y-Connector and Splash Shield Soft Cone contain less than 34% DEHP by weight, and the Small Suction Cone contains less than 39% DEHP by weight. These components are intended for indirect patient contact only and do not directly contact the patient during normal use. There is no potential patient harm associated with this issue.

Actions Needed from the Customers

1. Review your inventory to locate affected products at your facility.
2. If you have received this notice directly from Stryker, please complete and return the enclosed Business Reply Form (BRF) to XXXX@stryker.com, even if the affected product is no longer in your inventory. Although product return is not required for this recall, submitting the BRF prevents duplicate notices from being sent.
3. Once the completed Business Reply Form is received at XXXX@stryker.com, Stryker will issue a shipping label for the return of any recalled product currently on hand.
4. Credit will be provided upon receipt of the recalled product(s).
5. Maintain awareness of this communication internally and inform Stryker if any of the subject devices have been distributed to other organizations. If so, provide contact details so Stryker can inform the recipients accordingly.
6. Please inform us of any adverse events and/or report them to the Health/Competent Authorities in accordance with current regulations. For questions or concerns, please contact XXXX@stryker.com,

Your designated contact person for this action is given below. Should you have any queries concerning this matter please do not hesitate to contact them directly.

Name:

Position:

E-mail:

In line with the recommendations of the Medical Device Coordination Group Guidance document Ref MDCG 2023-3 and EU MDR 2017/745, we can confirm that this FSCA has been notified appropriately to the National Competent Authority for your country.

In accordance with the applicable RoHS requirements, appropriate corrective measures have been implemented to address the identified non-conformity. Based on our assessment, a recall of products already in the field was not deemed necessary. However, should you prefer to return the affected product, we will be happy to support you with the return process.

On behalf of Stryker, we thank you sincerely for your help and support in completing this action and regret any inconvenience caused. We would like to reassure you that Stryker is committed to ensuring that only conforming devices, meeting our high internal quality standards and your expectations, remain on the market.

7. Sincerely,

Business Reply Form

InterPulse®

Attn: Material Manager, OR Director, Risk Manager

Reference Number: RA2026-4390714

September XX 2026

Please select from the options below, note the quantities on hand as applicable, and complete this form.

Email the completed form to xxxx@stryker.com. **RESPONSE IS REQUIRED.**

- ☐ No remaining products affected on hand.
- ☐ I, the customer, choose to keep the impacted product(s).
- ☐ I, the customer, choose to return the following product(s) for credit:

Catalog Number	Product	Affected Lots	Quantity on hand (EA)
0210-010-000	Bone Cleaning Tip		
0210-010-100	Coaxial Bone Cleaning Tip with Soft Shield		
0210-014-100	Coaxial High Flow Tip with Soft Shield		
0210-018-000	Fan Spray Tip		
0210-014-000	High Flow Tip		
0210-110-100	InterPulse Handpiece Set with Coaxial Bone Cleaning Tip & Suction Tube		
0210-114-100	InterPulse Handpiece Set with Coaxial High Flow Tip & Suction Tube		
0210-158-000	InterPulse Handpiece Set with Coaxial Multi-Orifice Tip & Suction Tube		
0210-012-000	Soft Tissue Tip		
0210-110-000	InterPulse Handpiece Set with Bone Cleaning Tip & Suction Tube		
0210-114-000	InterPulse Handpiece Set with High Flow Tip & Suction Tube		
0210-112-000	InterPulse Handpiece Set with Soft Tissue Tip & Suction Tube		
0210-210-000	InterPulse Handpiece Set with Bone Cleaning Tip		
0203-030-000	Dual Irrigation Adaptor		
0210-118-100	InterPulse Handpiece Set with Coaxial Fan Spray Tip & Suction Tube		
0210-118-200	InterPulse Handpiece Set with Retractable Coaxial Fan Spray Tip & Suction Tube		
0210-118-000	InterPulse Handpiece Set with Fan Spray Tip & Suction Tube		
0207-066-000	Soft Cone Splash Shield 12/Box		

*If all devices have been used and no affected devices are available for return, please enter 0 (zero).

Form completed by:

Facility Name			
Facility Address			
Printed Name		Title	
Signature		Phone	
Date		Email	

Note: Your signature indicates that you have received and understand the enclosed notification and that you have performed all actions requested.

If you have further distributed any affected product, please indicate to whom:

Facility Name		Contact Person	
Full Address			

Appendix A

Bone Cleaning Tip (0210-010-000)								
23011012	23018012	23021012	23033012	23042012	23048012	23072012	23080012	23083022
23084012	23091012	23091032	23095012	23126012	23128012	23130012	23142012	23152012
23154012	23158012	23182012	23185012	23192012	23195012	23269012	23275012	23275022
23276012	23289012	23311012	23335012	24003012	24008012	24011012	24022012	24040012
24045012	24064012	24074012	24076012	24094012	24149012	24162012	24172012	24183012
24190012	24191012	24214012	24219012	24228012	24282012	24283012	24306012	24312012
24344012	25007012	25021012	25029012	25034012	25062012	25083012	25085012	25097012
25123012	25139012	25162012	25163012	25164012	25191012	25213012	25213022	25217012
25276012	25307012	25337012						

Coaxial Bone Cleaning Tip with Soft Shield (0210-010-100)								
23003012	23033012	23082012	23096012	23145012	23186012	23306012	23335012	23335022
24027012	24103012	24129012	24170012	24199012	24247012	24346012	25016012	25038012
25077012	25093012	25153012	25274012	25307012	25343012			

Coaxial High Flow Tip with Soft Shield (0210-014-100)								
23011022	23307012	23339012	23340012	23340022	24027012	24033012	24036012	24064012
24088012	24103012	24114012	24136012	24166012	24171012	24197012	24205012	24206012
24247012	25007012	25008012	25034012	25038012	25072012	25076012	25078012	25091012
25094012	25133012	25134012	25139012	25156012	25177012	25182012	25183012	25188012
25190012	25192012	25213012	25213022	25307012	25335012			

Fan Spray Tip (0210-018-000)								
23045012	23084012	23084022	23100012	23123022	24004012	24040012	24137012	24282012
25216012								

High Flow Tip (0210-014-000)								
23277012	23318012	23320012	23335012	23338012	23339012	23340012	23353012	23354012
24004012	24004022	24008012	24008022	24065012	24067012	24076012	24118012	24135012
24163012	24173012	24214012	24220012	24228012	24250012	24253012	24255012	24283012
24284012	24316012	24316022	24337012	24340012	25022012	25023012	25045012	25065012
25072012	25076012	25077012	25080012	25099012	25104012	25107012	25127012	25163012
25169012	25196012	25216022	25274012	25275012	25276012	25286012	25307012	

InterPulse Handpiece Set with Coaxial Bone Cleaning Tip & Suction Tube (0210-110-100)								
23311022	24052012	24052022	24057012	24086012	24109012	24129012	24129022	24129032
24150032	24204012	24253032	24260012	24361012	25016012	25017012	25017022	25027012
25028022	25036012	25044012	25044022	25045012	25049012	25050012	25111022	25114022
25115032	25118022	25118032	25118042	25148012	25148022	25148032	25149012	25150022
25188012	26064012							

InterPulse Handpiece Set with Coaxial High Flow Tip & Suction Tube (0210-114-100)								
23348012	24044012	24045022	24046032	24047012	24051022	24095012	24095032	24103032
24115022	24164032	24173022	24218012	24311022	25010012	25036012	25059012	25127032
25142012	25167032	25181072	25220012	25220022	25223012	25223022	25223032	25224022
25232012	25237012	25242012	25268032					

InterPulse Handpiece Set with Coaxial Multi-Orifice Tip & Suction Tube (0210-158-000)								
24029012	24029032	24033022	24073022	24106012	24106042	24128012	24142022	24165032
24166052	24177022	24185012	24186032	24201022	24270022	24351012	24353012	24353022
25009012	25020022	25028022	25031022	25037022	25044012	25077012	25094012	25107012
25119012	25154012	25189012	25198012	25226012	25227012	25302012		

Soft Tissue Tip (0210-012-000)								
23011012	23044012	23083012	23100012	23129012	23152012	23182012	23321012	23346012
24003012	24052012	24078012	24099012	24134012	24157012	24183012	24247012	24282012
25048012	25072012	25076012	25091012	25218012	25307012	25335012		

Appendix B

InterPulse Handpiece Set with Bone Cleaning Tip & Suction Tube (0210-110-000)								
24002022	24002052	24009042	24009082	24019012	24019022	24032022	24032032	24032042
24036012	24036042	24037012	24037022	24037032	24040012	24040022	24040032	24051012
24051022	24051032	24051042	24051052	24052012	24052032	24053012	24053022	24053032
24061012	24061022	24061032	24061042	24061052	24065022	24065032	24065042	24065052
24069012	24076012	24078012	24078022	24078032	24078052	24080012	24080022	24080032
24080042	24080052	24080062	24081012	24081022	24081032	24081042	24082012	24082022
24082032	24082042	24082052	24083012	24094012	24095022	24095032	24095052	24097012
24101012	24101032	24102012	24102032	24102042	24103012	24103022	24103032	24104012
24106012	24106022	24107022	24107032	24107042	24107052	24110012	24110022	24110032
24110042	24111012	24113012	24113022	24113032	24113042	24114012	24114022	24114032
24114042	24114052	24116012	24116052	24120012	24120022	24120032	24122012	24122032
24122052	24122062	24123012	24123022	24123032	24123042	24123052	24131012	24131022
24131032	24131042	24131052	24131062	24135012	24135022	24135032	24135042	24135052
24135062	24138012	24138022	24138032	24138042	24138052	24138062	24139012	24143012
24143022	24143042	24143052	24143062	24143072	24143082	24144012	24152012	24152022
24152032	24152042	24156012	24156022	24156032	24157012	24157032	24158012	24158022
24162022	24162032	24163022	24164022	24164032	24170012	24170022	24170032	24172012
24172022	24172032	24173012	24173032	24177012	24177022	24179012	24179022	24180012
24180022	24183012	24186022	24186032	24194012	24194022	24194032	24198012	24198022
24198032	24199012	24200012	24200022	24200032	24200042	24201012	24204012	24204022
24205012	24205022	24205032	24206022	24206032	24208012	24208032	24208042	24211012
24211022	24211032	24212012	24212022	24213012	24213022	24214012	24214022	24214032
24215012	24215022	24215032	24220012	24220022	24220032	24229012	24232012	24232022
24233022	24233032	24239012	24243012	24243032	24243042	24247012	24247022	24247032
24248012	24248022	24248032	24249012	24249022	24249032	24250012	24250022	24250032
24253032	24254012	24254022	24255012	24255022	24255032	24256012	24263012	24264012
24268012	24273012	24275012	24275022	24276012	24276022	24276032	24277012	24277022
24278012	24278022	24282012	24283012	24283022	24283032	24284012	24284022	24285012
24289012	24289022	24289032	24289042	24291012	24291022	24292022	24296032	24296052
24299012	24299022	24300012	24301012	24301022	24302012	24302022	24302032	24303022
24309012	24312012	24312022	24312032	24312042	24313012	24313022	24313032	24317012
24317022	24317032	24318012	24318032	24318042	24319012	24319022	24319032	24319042
24319052	24320012	24320022	24321012	24321022	24323012	24323022	24323032	24323042
24323052	24324012	24324022	24324032	24325022	24325032	24325042	24325052	24326012
24326022	24327022	24337012	24337032	24337052	24338012	24338022	24338032	24338072
24339012	24339022	24339032	24339042	24340012	24340022	24340032	24341012	24341022
24341042	24341052	24342012	24343012	24343022	24343032	24344012	24345012	24345022
24346012	24347012	24349012	24351012	24355012	24362012	24363012	24363022	25007012
25007022	25008012	25008022	25013012	25013022	25013032	25014012	25014022	25014032
25015012	25017012	25020012	25021012	25021022	25021032	25022012	25023022	25024012
25028022	25034012	25037012	25041012	25041022	25042012	25042022	25043012	25043022
25048012	25048022	25049022	25050012	25052032	25055012	25055022	25056012	25056022
25056032	25057012	25057022	25091012	25091022	25091032	25091042	25092012	25092022
25092032	25093012	25093032	25094012	25094022	25094032	25097012	25097022	25097032
25098022	25099012	25099022	25099032	25100012	25100022	25100032	25101012	25106012
25106022	25112012	25112022	25112032	25113012	25126012	25128012	25129012	25133012
25140012	25141012	25141022	25142012	25143012	25143022	25143032	25143042	25147012
25147032	25147042	25148012	25148022	25148032	25149012	25149022	25153012	25153022
25154012	25154022	25155022	25156012	25156022	25157022	25160022	25161022	25162022
25163012	25163022	25164012	25164022	25165012	25165022	25167012	25167022	25168012
25168022	25169012	25169022	25170022	25170032	25170042	25170052	25171012	25172012
25172022	25174022	25174032	25174042	25174052	25175012	25175022	25175032	25175042
25176022	25176032	25176042	25177012	25177022	25177032	25177042	25178012	25178022
25178032	25178042	25178052	25178062	25178072	25178082	25182032	25183012	25183022
25184012	25188012	25190012	25191012	25204012	25209012	25219012	25219022	25220012
25224012	25224022	25225012	25225022	25226012	25227012	25228022	25229012	25230012
25230022	25231012	25231022	25232012	25233012	25233022	25234012	25241012	25241022
25246012	25246022	25246032	25247032	25248012	25248022	25248032	25251012	25251032

25252012	25252022	25252032	25258012	25259012	25265012	25265022	25268012	25272012
25276012	25276022	25279012	25279022	25280012	25280032	25281012	25282012	25282022
25283012	25290012	25293012	25294012	25295032	25296012	25297012	25297022	25300012
25301012	25302012	25307012						

Appendix C

InterPulse Handpiece Set with High Flow Tip & Suction Tube (0210-114-000)								
24011012	24011022	24012012	24012042	24012052	24012072	24013022	24015012	24016032
24018032	24025012	24025052	24033032	24033042	24038022	24043012	24043022	24043032
24043042	24044022	24050022	24053012	24054022	24054032	24054042	24054052	24057012
24057022	24058022	24059012	24060042	24060062	24062012	24064042	24066012	24066022
24067032	24067042	24067052	24069022	24071022	24071032	24072012	24072042	24073032
24075042	24075052	24076012	24085052	24086012	24086042	24086052	24087072	24093032
24093052	24097012	24099022	24099032	24100032	24100052	24104012	24108022	24108042
24108052	24108062	24109012	24109022	24109032	24109052	24115012	24115032	24115042
24117012	24117022	24117032	24118012	24118022	24119012	24121012	24121022	24121042
24121052	24124022	24124032	24124042	24124052	24124062	24127012	24127022	24127062
24129012	24129022	24129042	24129052	24130012	24130052	24132022	24137012	24137022
24137042	24138012	24139012	24141022	24141032	24141052	24141062	24141072	24142042
24142052	24145022	24145062	24145072	24151012	24151032	24151052	24151062	24151082
24151092	24152022	24152032	24155012	24156012	24157022	24158012	24158022	24158032
24162012	24162032	24164012	24164022	24166012	24166022	24169012	24169032	24171012
24172012	24172032	24176042	24177012	24177032	24177042	24177052	24178012	24178022
24179012	24179022	24180022	24181022	24184012	24185022	24186012	24186022	24190012
24191012	24191032	24192032	24192042	24193012	24193022	24193032	24194032	24194042
24199012	24200022	24207022	24211012	24211022	24211042	24211052	24213012	24213022
24213042	24215012	24215022	24215032	24218012	24218032	24219022	24220012	24220022
24220032	24228022	24229022	24230012	24232022	24234022	24234032	24235022	24235052
24236042	24239042	24241022	24241042	24242052	24242062	24243022	24244032	24244052
24249012	24249022	24250022	24254022	24256012	24257012	24261022	24262012	24275022
24282012	24283012	24283032	24284012	24284022	24285012	24285022	24288012	24289022
24289032	24289042	24290032	24290042	24291012	24291022	24291032	24291042	24291052
24292012	24293022	24297022	24297032	24297052	24297072	24298032	24298042	24298052
24306012	24306032	24307012	24307022	24308012	24308022	24309022	24309032	24310012
24310022	24310032	24311012	24311022	24312012	24312022	24316032	24316042	24316072
24316082	24317022	24317032	24317052	24318032	24319012	24319022	24321032	24322022
24322032	24324022	24324032	24325012	24325032	24325042	24325052	24344012	24344022
24346022	24349022	24349032	24352012	24352032	24354022	24356012	24361012	24361022
25007022	25008012	25010032	25010042	25013012	25013022	25015012	25015032	25017012
25017032	25020012	25020022	25022022	25022032	25023012	25023022	25023042	25024022
25024032	25027012	25028022	25029012	25029052	25034012	25034022	25035012	25035022
25036022	25037012	25038012	25038032	25041012	25048022	25055012	25055022	25062032
25063012	25064012	25064032	25065012	25066012	25069032	25069042	25070022	25070032
25070042	25070052	25071012	25071022	25071052	25072012	25073012	25073042	25073052
25076032	25077012	25077022	25077032	25077042	25077052	25078022	25078052	25079012
25079042	25079052	25080022	25080042	25081012	25083012	25083022	25083042	25083062
25084012	25085022	25086022	25086032	25087012	25087022	25087052	25090022	25090052
25092022	25111012	25114012	25114042	25121032	25122022	25122032	25123012	25126012
25126022	25126032	25127022	25127032	25128012	25128032	25129012	25130012	25132012
25133012	25133022	25134022	25134052	25136022	25136032	25136042	25136062	25139012
25139042	25140022	25140032	25142012	25142022	25142032	25153012	25153022	25154022
25156022	25156032	25157032	25161012	25161032	25162032	25163032	25164012	25165022
25167032	25168012	25168022	25169022	25169032	25170032	25171012	25171032	25172022
25174022	25175012	25175042	25176012	25176042	25177022	25193012	25195012	25197012
25197032	25197042	25199022	25202032	25204012	25204022	25204032	25205012	25205032
25206022	25207012	25211032	25212022	25212032	25226012	25228012	25231022	25235012
25235022	25239012	25239032	25240012	25240032	25241022	25241032	25245012	25247012
25247022	25253012	25253022	25254012	25254022	25255012	25256022	25258012	25259022
25260012	25261012	25263012	25266012	25266032	25267012	25267022	25268012	25268022
25268032	25272012	25272022	25273012	25276012	25276022	25279012	25279022	25280022
25281012	25282032	25286012	25287012	25288012	25288022	25289012	25289022	25290012
25293012	25293022	25296012	25300012	25302012	26058042			

Appendix D

InterPulse Handpiece Set with Soft Tissue Tip & Suction Tube (0210-112-000)								
24024012	24024062	24028012	24036012	24036022	24036032	24036042	24037012	24037022
24037032	24037042	24043022	24043032	24043042	24044022	24044042	24068012	24068022
24068042	24068052	24074022	24074032	24074042	24074052	24085012	24085022	24128012
24155022	24155032	24155042	24157012	24159012	24159042	24163012	24201022	24201032
24207012	24207022	24229022	24229032	24232012	24237012	24237022	24240012	24257022
24261012	24262012	24268012	24278012	24278022	24278032	24285022	24288012	24288022
24300012	24300022	24304012	24304032	24313012	24316012	24326022	24327012	24327022
24327032	24337012	24338012	24340012	24341012	24354012	24356012	25042012	25044012
25044022	25045022	25049012	25050012	25057032	25059012	25065012	25065022	25065032
25066022	25091012	25093012	25093022	25095012	25098012	25098022	25099012	25100022
25101012	25101022	25104022	25105022	25106012	25106022	25107012	25107022	25113012
25113022	25114012	25118012	25118022	25119012	25120012	25125012	25143022	25143032
25147012	25147022	25150012	25150022	25150042	25182012	25182022	25200012	25200022
25210012								

InterPulse Handpiece Set with Bone Cleaning Tip (0210-210-000)								
23341012	23349012	24016012	24024012	24052012	24057012	24057022	24060012	24107012
24109012	24129012	24130012	24131012	24169012	24170012	24207012	24211012	24240012
24264012	24264022	24290012	24292012	24292022	24346012	24347012	24352012	25015012
25015022	25029012	25034012	25043012	25043022	25085012	25085022	25114012	25119012
25120012	25162012	25190012	25192012	25192022	25202012	25202022	25203012	25204012
25204022	25210012	25337012	25338012	25339012	25349012			

Dual Irrigation Adaptor (0203-030-000)	
24275012	24351012

InterPulse Handpiece Set with Coaxial Fan Spray Tip & Suction Tube (0210-118-100)				
25024012	25029022	25308012	25310012	25325012

InterPulse Handpiece Set with Retractable Coaxial Fan Spray Tip & Suction Tube (0210-118-200)		
25035012	25080022	25293012

InterPulse Handpiece Set with Fan Spray Tip & Suction Tube (0210-118-000)		
25237012	25237022	25238022

Soft Cone Splash Shield 12/Box (0207-066-000)				
18268012	22102012	23334012	24087012	25274012