



DENTECH CORPORATION  
53-5, Shinjuku-cho, Itabashi-ku,  
Tokyo 174-0053, Japan  
TEL:+81-3-3962-5621 FAX:+81-3-3962-5624  
E-MAIL: info@dentech.co.jp

Rev 1: April, 2021  
FSN Ref & FSCA Ref: 001

Date: 21/04/21

Urgent Field Safety Notice  
Rubber Dam Clamp no. 12A, no.13A, no.26  
(Glossy, Matt, Black)  
Risk of breakage

For Attention of\*: Chief Executive/Risk Management/Purchasing of  
Distributors, Authorized representative

**Contact details of local representative (name, e-mail, telephone, address etc.)\***

**DIRECT DENTAL SUPPLIES BV**  
Einsteinweg 31, 3404 LHIJSSELSTEIN, Netherland  
TEL:+31(0)30 68 74 077  
FAX:+31(0)30 68 74 001  
[info@directdentalsupplies.nl](mailto:info@directdentalsupplies.nl)



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<b>Information on Affected Devices*</b>	
1	1. Device Type(s)* Rubber Dam Clamp for dental treatment  The device is used with Dental Dam, Frame to prevent contamination by moisture or saliva during dental treatment. The device come in a range of types including several of the kit/set.
1	2. Commercial name(s) Rubber Dam Clamp
1	3. Unique Device Identifier(s) (UDI-DI) As per attached sheet(1)
1	4. Primary clinical purpose of device(s)* It is composed of instruments such as a dental rubber dam, a dental rubber dam clamp, a dental rubber dam forceps, and a dental rubber dam frame, and is used for prevention of contamination by saliva and moisture prevention during dental treatment.
1	5. Device Model/Catalogue/part number(s)* As per attached sheet (1)
1	6. Affected serial or lot number range As per attached sheet (2)


<b>Reason for Field Safety Corrective Action (FSCA)*</b>	
2.	1. Description of the product problem* Regarding these products, there was information on defects related to breakage of about 1 piece on average per annual production of about 300,000 pieces. Since number of cases increased significantly, we investigated and found that the above-mentioned Lot no of the products using specific materials, may have a particularly high rate of breakage, so we decided to voluntarily recall them.
2.	2. Hazard giving rise to the FSCA* This product is to be worn on the patient's teeth. If it breaks in the oral cavity, there is a risk of mucous membrane damage or accidental ingestion, but due to the nature of the product, it will break under the gaze of a dental professionals, so it is thought that appropriate measures will be taken immediately. Therefore, we do not think that it may lead to serious health damage. In addition, there are no reports of health hazards that may be caused by this incident in Japan and any other countries.



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Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p><input checked="" type="checkbox"/> Identify Device    <input checked="" type="checkbox"/> Quarantine Device    <input checked="" type="checkbox"/> Return Device    <input checked="" type="checkbox"/> Other</p> <p>-Please identify the products first by Lot no., Product Code, Shipment date.            - From the link below or by email, please inform DENTECH of total quantity of defective products with color distinction(Glossy, Matt, Black)            We will replace all of them free of charge. If you have any concerns about the items in your stock, We will also replace them.</p> <p><a href="https://forms.office.com/Pages/ResponsePage.aspx?id=AI_FWYBdHESbvUaTI-k1Hv9_PCITFe9HjvGUYz6cYkRURFJVQURQS1RSVUVVYVURWSkhNOEdNUzRIMCQIQCN0PWcu">https://forms.office.com/Pages/ResponsePage.aspx?id=AI_FWYBdHESbvUaTI-k1Hv9_PCITFe9HjvGUYz6cYkRURFJVQURQS1RSVUVVYVURWSkhNOEdNUzRIMCQIQCN0PWcu</a></p> <p>-If possible, please return the said products to us.            Returned Product should be addressed to :            (freight collect) FedEx A/C#1898-0590-0            (please choose international economy service)            DENTECH CORPORATION-            53-5, Shimizu-cho, Itabashi-ku, Tokyo, 174-0053, Japan            TEL: +81-3-3964-2011 Attn : Keiko Kashiyama / Mika Kato</p>
3.	<p>2. Is customer Reply Required? * (If yes, form attached specifying deadline for return)      Yes</p>
3.	<p>3. Action Being Taken by the Manufacturer</p> <p><input checked="" type="checkbox"/> Product Removal</p>

General Information*	
4.	1. FSN Type*      New
4.	2. Further advice or information already expected in follow-up FSN?      Yes *Lot Nos. will be added later
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name      DENTECH CORPORATION
	b. Address      53-5, Shimizu-cho, Itabashi-ku, Tokyo, 174-0053, Japan Tel:+81-3964-2011/Fax:+81-3964-5624
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *
4.	5. Name/Signature      DENTECH CORPORATION
	 Manager

Transmission of this Field Safety Notice	
	<p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)            Please transfer this notice to other organisations on which this action has an impact. (As appropriate)            Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.            Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback..*</p>

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.

**Template for a Field Safety Notice Distributor/Importer Reply Form**  
**Distributor/Importer Reply Form**

<b>1. Field Safety Notice (FSN) information</b>	
FSN Reference number*	4
FSN Date*	April 21, 2021
Product/ Device name*	RUBBER DAM CLAMP
Product Code(s)	01012912, 01014912, 01019912 01012913, 01014913, 01019913 01012026, 01014026, 01019026
Batch/Serial Number (s)	As per attached

<b>2. Distributor/Importer Details</b>	
Company Name*	
Account Number (if any changes)	
Address(if any changes)	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number(if any changes)	
Email(if any changes)	

<b>3. Return acknowledgement to Sender</b>	
Email	
Distributor/Importer Helpline	As mentioned above +81-3-3964-2011 +81-3-3962-5624
Postal Address	DENTECH CORPORATION 53-5, Shimizu-cho, Itabashi-ku, Tokyo 174-0053 Japan
Web Portal	<a href="https://www.dentech.co.jp/english/products_en">https://www.dentech.co.jp/english/products_en</a>
Deadline for returning the Distributor/Importer reply form*	

<b>4. Distributors/Importers (Tick all that apply)</b>		
<input type="checkbox"/>	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor/Importer to complete or enter N/A.
<input type="checkbox"/>	I have checked my stock and quarantined inventory	Distributor/Importer to enter quantity and date
<input type="checkbox"/>	I have identified customers that received or may have received this device	Distributor/Importer to enter <u>quantity of each products</u>
<input type="checkbox"/>	I have attached customer list	
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date of communication:

Rev 1: July 2018

<input type="checkbox"/>	I have received confirmation of reply from all identified customers	
<input type="checkbox"/>	I have returned affected devices - enter number of devices returned and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
<input type="checkbox"/>	I have destroyed affected devices – enter number destroyed and date complete.	Add quantity, Lot/Serial Number/Date Returned (same information as requested by the Customer Reply form
<input type="checkbox"/>	Neither I nor any of my customers has any affected devices in inventory	
Print Name*		Distributor/Importer print name here
Signature*		Distributor/Importer sign Here
Date *		

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.



-Attached sheet (1)

Commercial Name(s)		Rubber Dam Clamp no.12A	Rubber Dam Clamp no.13A	Rubber Dam Clamp no.26
				
Glossy	Product Code	01012912	01012913	01012026
	UDI-DI	04560218660961	04560218660978	04560218660183
Matt	Product Code	01014912	01014913	01014026
	UDI-DI	04560218669490	04560218669506	04560218669124
Black	Product Code	01019912	01019913	01019026
	UDI-DI	04560218672742	04560218672759	04560218672377

<Sample Label>



-Attached sheet (2)

**Product Name : Rubber Dam Clamp no.12A, Glossy (01012912)**

Lot No. :

189527904 18121014 190708016 200701018 190712085 190712043 190808016 190730025 190730036 190829013 190802028 190815021 190827005 191007004 191009022 191008040 191023003 190808010 190818086 191029047  
180314023 191147029 191144018 191121025 190825014 191121034 191029097 191029138 191029182 191030018 191203088 191116011 200204002 200202011 191206008 191206005 200214043 200214025 200219008 200202006  
200311015 200402007 191029023 191029026 191029038 200212023 200208007 200205028 191204006 191206022 201103015 191211025 200218036 191206073 191029031 200202010 191206128 201021075 191047006 191048005  
190527011 190522004 190524020 190526061 190526085 190530037 190531009 190535083 190400007 190400006 191000000 191000000

Quantity : 1217Pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.12A, Matt (01014912)**

Lot No. :

180813408 200711043 180918020 191111023 191114057 191020035 200121049 200211042 200603023 200816020 200217009 200711013 201001081 210418026 210210023 190610015 190226011 180907009 190405048 191019009  
181202001 190306001

Quantity : 70Pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.12A, Black (01019912)**

Lot No. :

191008021 191114056 191108036 191030008 200214041 200601022 200919018 190326052 200902084 210211041 191040023 190909084 190513002 190521029 190504019 180830016 190507053 180802028 180900013 181012012  
181207007 190504004

Quantity : 174 pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.12A, Glossy (01012913)**

Lot No. :

190718017 190712066 190712044 190805017 190722020 190730026 190801003 190711027 190909027 190815027 191024002 191020030 190217005 191008028 191016041 190818012 190818060 191029044 191107030  
191114023 191121026 191119018 191121005 191212024 191029088 191212139 191129143 191030019 191210089 200114012 200212012 191206011 191206045 200214046 191211016 200225009 190303006 200305007 200310036  
200402004 191029023 191029067 191029058 200404009 200422024 200529008 200526027 191204048 191206023 200108016 200629056 200819047 200817028 200819017 191206015 200806045 200912011 200919014 200712069  
200712013 200727040 200601023 200727023 191206129 200806049 200829074 200825062 191029470 201008029 200202047 191206029 200202057 200903128 201002031 200924044 191008002 191008006 190514013 190922023  
190522005 190524020 190526091 190530028 190530010 190506005 190606011 180910019 180909006 180804011 191009009 191003011 191003011 181101011

Quantity : 1427Pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.13A, Matt (01014913)**

Lot No. :

190813028 190731043 190819026 191114023 191118032 191128036 191030008 190714047 200214011 200801026 200619021 200731004 201001086 201113072 210113046 210118027 210212048 190814014 190828012 180902005  
181004029 181206003 191003003 190202003

Quantity : 88Pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.13A, Black (01019913)**

Lot No. :

191008025 191114023 191003003 200214035 200619028 200324042 201002118 201009097 201113028 201211029 201211025 190813008 190821030 190524020 190626077 190602011 180904013 181008013 181020005 191026043  
190909003

Quantity : 1017Pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.26, Glossy (01012026)**

Lot No. :

181103010 190821087 190709098 190712051 190726034 190805022 190709018 190716045 190813003 190827088 190927021 191002026 191009044 191016044 190816025 191029006 191118020 191210029 200108019 191212045 191212045  
190916026 190924024 191220043 191029101 191029142 191209186 191029022 191015131 191112029 191212042 191210063 191220018 200214017 200218016 191206003 200214074 200225012 191029027 191029070 191029012  
200225007 200222006 200226032 200229056 200430027 200619054 200622022 200606032 191029099 200629018 200210044 200212037 200901033 191029096 191206042 191206042 200919034 200728051 200817008 200914015  
191029046 191229081 200201058 200904064 201009030 201222056 200203048 201202070 200823123 201008051 191029054 201008029 200824047 201002041 200902088 201002088 201206010 191029002 201029039 201014048

Quantity : 1089Pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.26, Matt (01014026)**

Lot No. :

190815044 191114047 191030039 200214071 200622076 190813002 190929019 180748016 180748056 181100011 181209019 190103007

Quantity : 791 pcs

Shipping date : 2018.8.30

**Product Name : Rubber Dam Clamp no.26, Black (01019026)**

Lot No. :

191009036 191008043 190513001 190626085 180601010 180808011 180905005 181102007 1802001

Quantity : 370 pcs

Shipping date : 2018.8.30

\* Lot Nos. will be added. Additional information will be sent to you as soon as prepared.