

6<sup>th</sup> July 2021

**URGENT: FIELD SAFETY NOTICE –PI-21-4115**

**Ecoflex Baskets, High Flex Baskets and Gastrotop Bile Endoprosthesis Sets**

**REF & Lot Numbers:** See Appendix 1

**Type of Action:** Product Removal

**Attention: Clinical Personnel, Risk Managers, Biomedical Personnel**

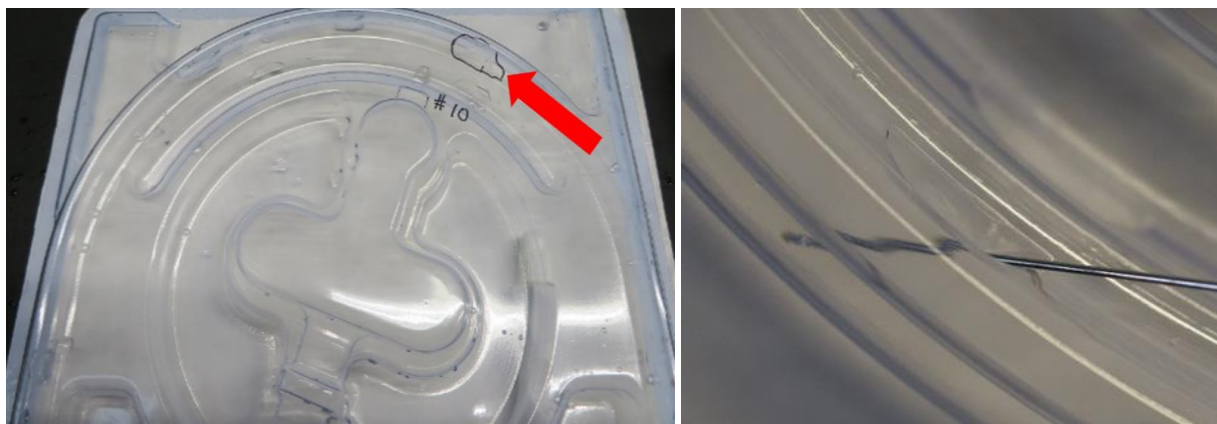
This letter contains important information which requires your **immediate** attention.

Dear Customer,

BD is conducting a Field Safety Corrective Action to remove specific lots of Angiomed GmbH & Co. Medizintechnik KG (a wholly owned subsidiary of Becton Dickinson and Company (BD)) **Ecoflex Baskets, High Flex Baskets and Gastrotop Bile Endoprosthesis Sets**. According to our distribution records your organisation may have received the impacted product.

**Description of the Problem**

The impacted **Ecoflex Baskets, High Flex Baskets and Gastrotop Bile Endoprosthesis Sets** are being removed as BD has become aware, through testing, of a pinhole type of defect on the products' packaging tray; potentially compromising the sterility of the product. BD estimates, based on product testing that approximately 50% of the product may be impacted. There have been no customer reports associated with this issue to date. Illustrations of the defect can be referenced in the following pictures:





This product removal is limited to the product code / lot numbers listed in Appendix 1. No other product codes or lot numbers are affected. Appendix 2 shows the location of the product code/lot number.

### **Clinical Impact**

This defect could result in health consequences including a varying degree of infection. Management of the patient, including but not limited to administration of antimicrobial therapy and any patient follow-up, is at the discretion of the treating physician. BD is not aware of any reports of adverse events associated with this product issue.

### **Advice on actions to be taken by the Customer:**

1. Inspect your inventory, locate, quarantine and destroy any units of the impacted Ecoflex Baskets, Gastrotop Bile Endoprosthesis Sets and High Flex Baskets lot numbers listed in Appendix 1.
2. If you have further distributed the product, please identify those facilities, notify them at once of this product removal and have them destroy the affected product.
3. Complete the customer response form on page 3 indicating:
  - o the quantities destroyed **OR**
  - o that your organisation does not have any impacted units left in inventory
4. Return the completed customer response form to <<insert contact details here>> for replacement product **as soon as possible or no later than 6<sup>th</sup> August 2021.**

### **Contact Reference Person**

If you have any questions about this, please contact your local BD representative or the local BD office on <<insert telephone details here>> or e-mail <<insert contact email address here>>.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to advancing the world of health. Our primary objectives are patient safety and user safety and providing you with quality products. We apologise for the inconvenience this situation may cause you and thank you in advance for helping BD to resolve this matter as quickly and effectively as possible.

Sincerely,

xxx



## Customer Response Form - PI-21-4115

### Ecoflex / High Flex Baskets and Gastrotop Bile Endoprosthesis Sets

REF & Lot Numbers: See Appendix 1

Please read in conjunction with Field Safety Notice PI-21-4115 and return completed and signed form as soon as possible or **no later than the 6<sup>th</sup> August 2021** to <<insert fax/email address here>>.

- I confirm this notice has been read, understood and that all recommended actions have been implemented as required.

*Tick the appropriate box below*

We do not have any of the affected product as listed in Appendix 1 in our possession.

**OR**

We have the following units of the affected product as listed in Appendix 1 in our possession and I confirm that the units have been destroyed (*Please complete Appendix 1 with the number of units destroyed and return with your response form in order for replacement product to be provided*).

<b>Account/Organisation Name:</b>	
<b>Department (if applicable):</b>	
<b>Address:</b>	
<b>Postcode:</b>	<b>City:</b>
<b>Contact Name:</b>	
<b>Job Title:</b>	
<b>Contact Telephone Number:</b>	<b>Contact E-mail Address:</b>
<b>Signature:</b>	<b>Date:</b>

*This form must be returned to BD before this action can be considered closed for your account.*



## Appendix 1 – Impacted Product Code / Lot numbers

### GASTROTOP Bile Endoprosthesis Sets

Product Name	Product Code (REF)	Lot Number	Product Description	Product Expiration Date	Number of Units Destroyed
GASTROTOP Bile Endoprosthesis Set	36220010	ANER3982	GT-SP 8/15	24-Apr-23	
	36430010	ANEU4273	GT-DP 9/ 4	31-Jul-23	
		ANEV0629	GT-DP 9/ 4	07-Aug-23	
	36430020	ANEU4270	GT-DP 9/ 7	31-Jul-23	
		ANEV0635	GT-DP 9/ 7	07-Aug-23	

### ECOFLEX BASKETS

Product Name	Product Code (REF)	Lot Number	Product Description	Product Expiration Date	Number of Units Destroyed
ECOFLEX BASKET	42285080	ANEU0615	EFK 4,0/20/30/ 90/5	03-Jul-23	
	42245060	ANEQ3802	EFK 2,5/10/20/ 90/4/H	20-Mar-23	
	42245070	ANEW3001	EFK 2,5/15/25/ 90/4/H	18-Sep-23	
		ANEX4445	EFK 2,5/15/25/ 90/4/H	23-Oct-23	
		ANEX4446	EFK 2,5/15/25/ 90/4/H	23-Oct-23	
		ANEP4974	EFK 2,5/15/25/ 90/4/H	28-Feb-23	
		ANEP4978	EFK 2,5/15/25/ 90/4/H	28-Feb-23	
		ANEP4988	EFK 2,5/15/25/ 90/4/H	28-Feb-23	
		ANEQ3803	EFK 2,5/15/25/ 90/4/H	20-Mar-23	
		ANEQ3805	EFK 2,5/15/25/ 90/4/H	20-Mar-23	
		ANEQ3807	EFK 2,5/15/25/ 90/4/H	20-Mar-23	
		ANEQ3809	EFK 2,5/15/25/ 90/4/H	20-Mar-23	
		ANER2601	EFK 2,5/15/25/ 90/4/H	17-Apr-23	
		ANER1609	EFK 2,5/15/25/ 90/4/H	10-Apr-23	
		ANER3991	EFK 2,5/15/25/ 90/4/H	24-Apr-23	
		ANER2603	EFK 2,5/15/25/ 90/4/H	17-Apr-23	
		ANER2606	EFK 2,5/15/25/ 90/4/H	17-Apr-23	



		ANER3992	EFK 2,5/15/25/ 90/4/H	24-Apr-23	
		ANER3994	EFK 2,5/15/25/ 90/4/H	24-Apr-23	
		ANER3995	EFK 2,5/15/25/ 90/4/H	24-Apr-23	
		ANES3926	EFK 2,5/15/25/ 90/4/H	29-May-23	
		ANEU3335	EFK 2,5/15/25/ 90/4/H	24-Jul-23	
		ANEU4277	EFK 2,5/15/25/ 90/4/H	31-Jul-23	
		ANEV0639	EFK 2,5/15/25/ 90/4/H	07-Aug-23	
		ANEV2879	EFK 2,5/15/25/ 90/4/H	21-Aug-23	
		ANEV1908	EFK 2,5/15/25/ 90/4/H	14-Aug-23	

## HIGHFLEX BASKETS

Product Name	Product Code (REF)	Lot Number	Product Description	Product Expiration Date	Number of Units Destroyed
HIGH FLEX Baskets	42240010	ANER4854	HFK 2,5F/10/20/ 65/3/H	30-Apr-23	
	42240060	ANEP4989	HFK 2,5F/10/20/ 90/3/H	28-Feb-23	
	42240070	ANES1983	HFK 2,5F/15/25/90/30/H	15-May-23	
	42241060	ANEP2560	HFK 2,5F/10/20/ 90/4/H	14-Feb-23	
		ANEP4972	HFK 2,5F/10/20/ 90/4/H	28-Feb-23	
		ANEP4976	HFK 2,5F/10/20/ 90/4/H	28-Feb-23	
		ANEP4980	HFK 2,5F/10/20/ 90/4/H	28-Feb-23	
		ANEP4983	HFK 2,5F/10/20/ 90/4/H	28-Feb-23	
		ANEP4987	HFK 2,5F/10/20/ 90/4/H	28-Feb-23	
		ANEQ0918	HFK 2,5F/10/20/ 90/4/H	06-Mar-23	
	42241070	ANEW1595	HFK 2,5F/15/25/ 90/4/H	11-Sep-23	
		ANEW2999	HFK 2,5F/15/25/ 90/4/H	18-Sep-23	
		ANEW1598	HFK 2,5F/15/25/ 90/4/H	11-Sep-23	
		ANEW2995	HFK 2,5F/15/25/ 90/4/H	18-Sep-23	
		ANEW2997	HFK 2,5F/15/25/ 90/4/H	18-Sep-23	
		ANEW1599	HFK 2,5F/15/25/ 90/4/H	11-Sep-23	
		ANEX4442	HFK 2,5F/15/25/ 90/4/H	23-Oct-23	
		ANEX5669	HFK 2,5F/15/25/ 90/4/H	30-Oct-23	
		ANEX5672	HFK 2,5F/15/25/ 90/4/H	30-Oct-23	
		ANEP2558	HFK 2,5F/15/25/ 90/4/H	14-Feb-23	
ANEP2561	HFK 2,5F/15/25/ 90/4/H	14-Feb-23			



HIGH FLEX Baskets	42241070	ANEP4973	HFK 2,5F/15/25/ 90/4/H	28-Feb-23	
		ANEP4977	HFK 2,5F/15/25/ 90/4/H	28-Feb-23	
		ANEP4981	HFK 2,5F/15/25/ 90/4/H	28-Feb-23	
		ANES0838	HFK 2,5F/15/25/ 90/4/H	08-May-23	
		ANES0840	HFK 2,5F/15/25/ 90/4/H	08-May-23	
		ANES1981	HFK 2,5F/15/25/ 90/4/H	15-May-23	
		ANES1987	HFK 2,5F/15/25/ 90/4/H	15-May-23	
		ANES1986	HFK 2,5F/15/25/ 90/4/H	15-May-23	
		ANES2818	HFK 2,5F/15/25/ 90/4/H	20-May-23	
		ANES2822	HFK 2,5F/15/25/ 90/4/H	20-May-23	
	42241110	ANET3664	HFK 2,5F/10/20/120/4/H	26-Jun-23	
	42241120	ANEP2562	HFK 2,5F/15/25/120/4/H	14-Feb-23	
		ANEP4984	HFK 2,5F/15/25/120/4/H	28-Feb-23	
		ANER4860	HFK 2,5F/15/25/120/4/H	30-Apr-23	
		ANES2819	HFK 2,5F/15/25/120/4/H	20-May-23	
		ANES2823	HFK 2,5F/15/25/120/4/H	20-May-23	
		ANET0715	HFK 2,5F/15/25/120/4/H	05-Jun-23	
	42245010	ANEQ5143	EFK 2,5/10/20/ 65/4/H	27-Mar-23	
		ANER2604	EFK 2,5/10/20/ 65/4/H	17-Apr-23	
		ANES3924	EFK 2,5/10/20/ 65/4/H	29-May-23	
		ANES3925	EFK 2,5/10/20/ 65/4/H	29-May-23	
		ANET0718	EFK 2,5/10/20/ 65/4/H	05-Jun-23	
		ANET0719	EFK 2,5/10/20/ 65/4/H	05-Jun-23	
		ANET1656	EFK 2,5/10/20/ 65/4/H	12-Jun-23	
	42251030	ANET2655	HFK 4,0F/20/30/ 65/4/H	19-Jun-23	
	42251080	ANEP4990	HFK 4,0F/20/30/ 90/4/H	28-Feb-23	
		ANEQ3808	HFK 4,0F/20/30/ 90/4/H	20-Mar-23	
		ANEQ3804	HFK 4,0F/20/30/90/4/H	20-Mar-23	
		ANET3663	HFK 4,0F/20/30/ 90/4/H	26-Jun-23	
		ANEU0614	HFK 4,0F/20/30/ 90/4/H	03-Jul-23	
	42252030	ANEQ2454	HFK 4,0F/20/30/ 65/5/H	13-Mar-23	
		ANER0633	HFK 4,0F/20/30/ 65/5/H	03-Apr-23	
ANER4855		HFK 4,0F/20/30/ 65/5/H	30-Apr-23		
ANEU0610		HFK 4,0F/20/30/ 65/5/H	03-Jul-23		



HIGH FLEX  
Baskets

	ANEU1366	HFK 4,0F/20/30/ 65/5/H	10-Jul-23	
42252080	ANEV2880	HFK 4,0F/20/30/ 90/5/H	21-Aug-23	
	ANEY1794	HFK 4,0F/20/30/ 90/5/H	12-Nov-23	
	ANEP2563	HFK 4,0F/20/30/ 90/5/H	14-Feb-23	
	ANEQ2459	HFK 4,0F/20/30/ 90/5/H	13-Mar-23	
	ANER3998	HFK 4,0F/20/30/ 90/5/H	24-Apr-23	
	ANER4858	HFK 4,0F/20/30/ 90/5/H	30-Apr-23	
42263030	ANER0635	HFK 4,6F/20/30/ 65/6/H	03-Apr-23	
42270060	ANEW2996	HFK 2,5F/10/20/ 90/3	18-Sep-23	
	ANEX4440	HFK 2,5F/10/20/ 90/3	23-Oct-23	
	ANET3665	HFK 2,5F/10/20/ 90/3	26-Jun-23	
42270070	ANER4856	HFK 2,5F/15/25/ 90/3	30-Apr-23	
	ANET1650	HFK 2,5F/15/25/ 90/3	12-Jun-23	
	ANEU0611	HFK 2,5F/15/25/ 90/3	03-Jul-23	
42270110	ANEQ5147	HFK 2,5F/10/20/120/3	27-Mar-23	
	ANER2600	HFK 2,5F/10/20/120/3	17-Apr-23	
	ANER1613	HFK 2,5F/10/20/120/3	10-Apr-23	
42271010	ANEZ1838	HFK 2,5F/10/20/ 65/4	11-Dec-23	
	ANEZ3173	HFK 2,5F/10/20/ 65/4	17-Dec-23	
	ANEQ0914	HFK 2,5F/10/20/ 65/4	06-Mar-23	
	ANEQ0915	HFK 2,5F/10/20/ 65/4	06-Mar-23	
	ANEQ0925	HFK 2,5F/10/20/ 65/4	06-Mar-23	
	ANEQ0926	HFK 2,5F/10/20/ 65/4	06-Mar-23	
	ANEQ2452	HFK 2,5F/10/20/ 65/4	13-Mar-23	
	ANEQ2458	HFK 2,5F/10/20/ 65/4	13-Mar-23	
	ANES1979	HFK 2,5F/10/20/ 65/4	15-May-23	
	ANES2820	HFK 2,5F/10/20/ 65/4	20-May-23	
ANEV2881	HFK 2,5F/10/20/ 65/4	21-Aug-23		
42771020	ANEQ5275	HFK 2,5F/15/25/ 65/4	27-Mar-23	
	ANER0630	HFK 2,5F/15/25/ 65/4	03-Apr-23	
	ANER4851	HFK 2,5F/15/25/ 65/4	30-Apr-23	
	ANEW0650	HFK 2,5F/10/20/ 90/4	04-Sep-23	
	ANEV1906	HFK 2,5F/10/20/ 90/4	14-Aug-23	
	ANEV3791	HFK 2,5F/10/20/ 90/4	28-Aug-23	
	ANEW3000	HFK 2,5F/10/20/ 90/4	18-Sep-23	
	ANEW1597	HFK 2,5F/10/20/ 90/4	11-Sep-23	



HIGH FLEX  
Baskets

42271060

42271070

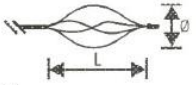

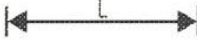
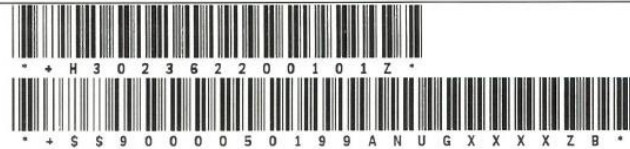
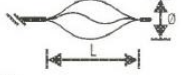

ANEX0388	HFK 2,5F/10/20/ 90/4	02-Oct-23	
ANEX0393	HFK 2,5F/10/20/ 90/4	02-Oct-23	
ANEX1771	HFK 2,5F/10/20/ 90/4	09-Oct-23	
ANEX3275	HFK 2,5F/10/20/ 90/4	16-Oct-23	
ANEY1790	HFK 2,5F/10/20/ 90/4	12-Nov-23	
ANEY3336	HFK 2,5F/10/20/ 90/4	20-Nov-23	
ANEY4411	HFK 2,5F/10/20/ 90/4	27-Nov-23	
ANEZ1839	HFK 2,5F/10/20/ 90/4	11-Dec-23	
ANEZ3174	HFK 2,5F/10/20/ 90/4	17-Dec-23	
ANEZ3175	HFK 2,5F/10/20/ 90/4	17-Dec-23	
ANFN1246	HFK 2,5F/10/20/ 90/4	14-Jan-24	
ANEP4982	HFK 2,5F/10/20/ 90/4	28-Feb-23	
ANEP4975	HFK 2,5F/10/20/ 90/4	28-Feb-23	
ANER0631	HFK 2,5F/10/20/ 90/4	03-Apr-23	
ANER1612	HFK 2,5F/10/20/ 90/4	10-Apr-23	
ANER1611	HFK 2,5F/10/20/ 90/4	10-Apr-23	
ANER2602	HFK 2,5F/10/20/ 90/4	17-Apr-23	
ANES3927	HFK 2,5F/10/20/ 90/4	29-May-23	
ANET1651	HFK 2,5F/10/20/ 90/4	12-Jun-23	
ANET2654	HFK 2,5F/10/20/ 90/4	19-Jun-23	
ANEU0607	HFK 2,5F/10/20/ 90/4	03-Jul-23	
ANEU3333	HFK 2,5F/10/20/ 90/4	24-Jul-23	
ANEU4275	HFK 2,5F/10/20/ 90/4	31-Jul-23	
ANEU4276	HFK 2,5F/10/20/ 90/4	31-Jul-23	
ANEU4278	HFK 2,5F/10/20/ 90/4	31-Jul-23	
ANEV0645	HFK 2,5F/15/25/ 90/4	07-Aug-23	
ANEY1796	HFK 2,5F/15/25/ 90/4	12-Nov-23	
ANEP2559	HFK 2,5F/15/25/ 90/4	14-Feb-23	
ANEQ0917	HFK 2,5F/15/25/ 90/4	06-Mar-23	
ANEQ0922	HFK 2,5F/15/25/ 90/4	06-Mar-23	
ANEQ0924	HFK 2,5F/15/25/ 90/4	06-Mar-23	
ANEQ2450	HFK 2,5F/15/25/ 90/4	13-Mar-23	
ANEQ2455	HFK 2,5F/15/25/ 90/4	13-Mar-23	
ANEQ2457	HFK 2,5F/15/25/ 90/4	13-Mar-23	
ANER4852	HFK 2,5F/15/25/ 90/4	30-Apr-23	
ANET1652	HFK 2,5F/15/25/ 90/4	12-Jun-23	





HIGH FLEX Baskets		ANEU1367	HFK 2,5F/15/25/ 90/4	10-Jul-23	
		ANEU2175	HFK 2,5F/15/25/ 90/4	17-Jul-23	
	42271110	ANEQ0916	HFK 2,5F/10/20/120/4	06-Mar-23	
		ANER4859	HFK 2,5F/10/20/120/4	30-Apr-23	
	42271120	ANEQ3806	HFK 2,5F/15/25/120/4	20-Mar-23	
		ANEX1770	HFK 4,0F/20/30/ 90/4	09-Oct-23	
		ANEX4448	HFK 4,0F/20/30/ 90/4	23-Oct-23	
	42281080	ANEY1789	HFK 4,0F/20/30/ 90/4	12-Nov-23	
		ANEY4409	HFK 4,0F/20/30/ 90/4	27-Nov-23	
		ANFN1248	HFK 4,0F/20/30/ 90/4	14-Jan-24	
		ANEQ3810	HFK 4,0F/20/30/ 90/4	20-Mar-23	
		ANEQ3811	HFK 4,0F/20/30/ 90/4	20-Mar-23	
	42282030	ANER4861	HFK 4,0F/20/30/ 65/5	30-Apr-23	
	42282080	ANES1984	HFK 4,0F/20/30/ 90/5	15-May-23	
		ANEP4985	HFK 4,6F/20/30/ 90/6	28-Feb-23	
	42293080	ANER4857	HFK 4,6F/20/30/ 90/6	30-Apr-23	
		ANET0717	HFK 4,6F/20/30/ 90/6	05-Jun-23	
		ANEU1365	HFK 4,6F/20/30/ 90/6	10-Jul-23	
		ANEU1368	HFK 4,6F/20/30/ 90/6	10-Jul-23	

## Appendix 2 - Product Code / Lot number Identification

Representative Labels	
<p><b>ECOFLEX</b>            basket, helical            panier, hélicoïdal            Körbchen, helikal            cestino, elicoidale            cesta, espiral            korfje, spiraalvormig</p> <p>Inv. chart            Patient chart            angiomed ECOFLEX BASKET            4-wire, 2.5F-cath. - 65cm            REF 42245010 LOT ANUGXXXX            angiomed ECOFLEX BASKET            4-wire, 2.5F-cath. - 65cm            REF 42245010 LOT ANUGXXXX</p>  <p>wire / fil /            Draht / filo /            guia / draad</p> <p>catheter / cathéter /            Katheter / catetere /            catéter / katheter</p> <p>10mm            20mm            4            2,5F[0,83mm]            65cm</p> <p>REF 42245010 2999-01 LOT ANUGXXXX 2999-01</p>  <p>+ * H 3 0 2 4 2 2 4 5 0 1 0 0 *            * + \$ \$ 9 0 0 0 0 1 0 1 9 9 A N U G X X X X A *</p> <p>CE            2797</p> <p>804980            Vers. 3/03-98</p>	<p><b>Product Code</b></p> <p><b>Lot Number</b></p>
<p><b>GASTROTOP</b>            Biliary Endoprosthesis Set            Kit d'Endoprothèse Biliaire            Gallen-Endoprothesen Set            Set Endoprotesi Biliare            Equipo de Endoprotésis Biliar            Gal-Endoprothese-Set</p> <p>Inv. chart            Patient chart            angiomed GASTROTOP-biliary stent - set            *SINGLE PIGTAIL MODEL*            REF 36220010 LOT ANUGXXXX            angiomed GASTROTOP-biliary stent - set            *SINGLE PIGTAIL MODEL*            REF 36220010 LOT ANUGXXXX</p>  <p>single pigtail/pigtail unique/Einfachpigtail/            pigtail singolo/pigtail sencillo/enkelvoudige pigtail</p> <p>15cm            8F[2,67mm]</p> <p>REF 36220010 2999-01 LOT ANUGXXXX 2999-01</p>  <p>+ * H 3 0 2 3 6 2 2 0 0 1 0 1 Z *            * + \$ \$ 9 0 0 0 0 5 0 1 9 9 A N U G X X X X Z B *</p> <p>CE            2797</p> <p>804980            Vers. 3/03-98</p>	<p><b>Product Code</b></p> <p><b>Lot Number</b></p>
<p><b>HIGHFLEX</b>            basket, helical            panier, hélicoïdal            Körbchen, helikal            cestino, elicoidale            cesta, espiral            korfje, spiraalvormig</p> <p>Inv. chart            Patient chart            angiomed High flex basket            3-wire, 2.5F-cath. - 65cm;            REF 42240010 LOT ANUGXXXX            angiomed High flex basket            3-wire, 2.5F-cath. - 65cm;            REF 42240010 LOT ANUGXXXX</p>  <p>wire / fil /            Draht / filo /            guia / draad</p> <p>catheter / cathéter /            Katheter / catetere /            catéter / katheter</p> <p>10mm            20mm            3            2,5F[0,83mm]            65cm</p> <p>REF 42240010 2999-01-01 LOT ANUGXXXX 2999-01-01</p>  <p>(01)0080174117664 7 (17)990101 (10)ANUGXXXX</p> <p>CE            2797</p> <p>804980            Vers. 3/03-98</p>	<p><b>Product Code</b></p> <p><b>Lot Number</b></p>