

	TECHNICAL FORM	ENR/11/38 – Ind 1 – 05/10/16	
		FT-MIKR-EN	Rev: 6
		Date: 04/03/19	P 1 / 4

**PRODUCT: FLEXIBLE MICRO CANNULA FOR FILLER INJECTION
KR HUB**

1. ADMINISTRATIVE INFORMATION ON THE COMPANY		
1.1	Name: Aesthetic Group	
1.2	Address: ZA La Gobette 60540 Puisseux Le Hauberger France	Phone: +33 03 44 74 19 95 Fax: +33 03 44 74 18 94 e-mail: info@aestheticgroup.fr Web site: www.aestheticgroup.fr
1.3	Materiovigilance contact details: François Baptendier	Phone: +33 03 44 74 19 95 Fax: +33 03 44 74 18 94 e-mail: info@aestheticgroup.fr

2. INFORMATION ABOUT THE DEVICE OR EQUIPMENT:																																									
2.1	Name: Micro cannula for filler injection with KR hub																																								
2.2	Tradename: Flexible micro cannula																																								
2.3	Nomenclature code: GMDN: 46676 HS Code: 90183900																																								
2.4	LPPR code (if applicable): N/A																																								
2.5	DM Class: IIa – Rule 7 EU Directive applicable: 93/42/CEE Number of the notified body: 1014 Date of first entry on the market in the EU: 2010 DM manufacturer: Aesthetic Group According to Annex No. II																																								
2.6	Description of the device: The flexible micro cannulas are used to inject a filler (synthetic or autologous fat) under the skin. Thanks to its flexibility the user can easily enter under the skin and treat large areas radiating from the entry point. Micro cannulas have blunt tips in order to avoid altering tissues and affecting nerves or vessels as with needles. It is the right balance between flexibility and rigidity. They are available in a wide selection of diameters and lengths from 30G to 18G and 25 to 110 mm length. The cannula hub is fitted with a Luer Lock, which is ergonomic and highly secure preventing disconnection during use. They have high quality, thin-walled steel tube with smooth surface. The hub is color-coded according to diameter.																																								
2.7	Catalogue reference: <table><tr><th>REFERENCE</th><th>GAUGE</th><th>OUTER DIAMETER (mm)</th><th>INNER DIAMETE R (mm)</th><th>USEFUL LENGTH (mm)</th><th>COLOR</th><th>PORT LENGTH (mm)</th></tr><tr><td>MI1870KR</td><td>18</td><td>1,25</td><td>1,05</td><td>70</td><td>Pink</td><td>1,00</td></tr><tr><td>MI1890KR</td><td>18</td><td>1,25</td><td>1,05</td><td>90</td><td>Pink</td><td>1,00</td></tr><tr><td>MI18110KR</td><td>18</td><td>1,25</td><td>1,05</td><td>110</td><td>Pink</td><td>1,00</td></tr><tr><td>MI2140KR</td><td>21</td><td>0,81</td><td>0,61</td><td>40</td><td>Green</td><td>1,00</td></tr></table>						REFERENCE	GAUGE	OUTER DIAMETER (mm)	INNER DIAMETE R (mm)	USEFUL LENGTH (mm)	COLOR	PORT LENGTH (mm)	MI1870KR	18	1,25	1,05	70	Pink	1,00	MI1890KR	18	1,25	1,05	90	Pink	1,00	MI18110KR	18	1,25	1,05	110	Pink	1,00	MI2140KR	21	0,81	0,61	40	Green	1,00
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MI2170KR	21	0,81	0,61	70	Green	1,00
MI2250KR	22	0,70	0,52	50	Black	1,00
MI2270KR	22	0,70	0,52	70	Black	1,00
MI2290KR	22	0,70	0,52	90	Black	1,00
MI2350KR	23	0,63	0,41	50	Blue	1,00
MI2370KR	23	0,63	0,41	70	Blue	1,00
MI2438KR	24	0,55	0,35	38	Purple	0,50
MI2450KR	24	0,55	0,35	50	Purple	0,50
MI2525KR	25	0,50	0,35	25	Orange	0,50
MI2538KR	25	0,50	0,35	38	Orange	0,50
MI2550KR	25	0,50	0,35	50	Orange	0,50
MI2625KR	26	0,45	0,25	25	Brown	0,50
MI2638KR	26	0,45	0,25	38	Brown	0,50
MI2650KR	26	0,45	0,25	50	Brown	0,50
MI2725KR	27	0,40	0,25	25	Grey	0,50
MI2740KR	27	0,40	0,25	40	Grey	0,50
MI2750KR	27	0,40	0,25	50	Grey	0,50
MI3025KR	30	0,30	0,15	25	Yellow	0,50

Packaging:

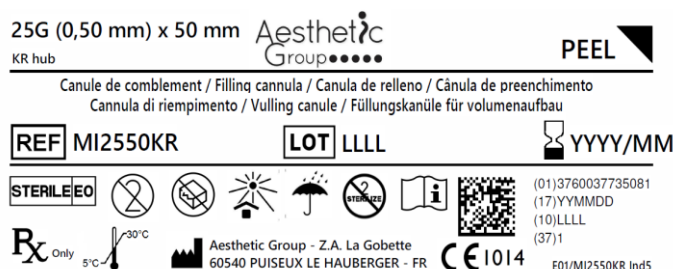
OU (Order Unit): Pouch of 1 piece

CDT (Multiple of OU): Boxes of 20 pieces

MDQ (Minimum Delivery Quantity): 1 box of 20 pieces

Aesthetic Group micro cannulas are packaged in single soft blister. This soft blister is composed of:

- A transparent upper sheet made of PA/PE. It permits a quick identification of the content. It mentions the necessary indications of content's identification: designation, item code, manufacture date ...
- An opaque lower sheet made of very resistant medical quality paper and adapted to the ethylene oxide sterilization.

Labelling:


2.8

Composition of the device and accessories:

The metallic tube

The metal tube is medical grade stainless steel (inox AISI 304). The injection cannulas have a atraumatic blunt end that safeguards the neurovascular axis of small diameter; and has an injection port at a distal end.

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	<p>The hub</p> <p>The hub is made of polycarbonate coloured in accordance with ISO 6009. This Luer Lock hub can fit any accessory with a male Luer lock end. A notch on the base identifies the port on the cannula.</p> <p>Latex: Presence Absence</p> <p>Phthalate (DHP): Presence Absence</p> <p>Products of animal or biological origin: Presence Absence</p> <p>Associated devices and accessories:</p> <p>Aesthetic Group micro cannulas are intended for use in combination with a syringe.</p>
2.9	<p>Field - Indications:</p> <p>Aesthetic Group micro cannula is a single use medical device exclusively dedicated to the injection of filler under the skin.</p> <p>It has a metallic tube with easily slide. Different lengths and diameters are available to suit all kinds of applications.</p>

3. STERILIZATION PROCESS

	<p>DM sterile: YES NO</p> <p>Sterilization method of the device: ETO</p>
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4. PRESERVATION AND STORAGE

	<p>Store in a clean and dry place at room temperature.</p> <p>Keep away from moisture and light</p> <p>Store in the original package</p> <p>Do not use if package is opened or damaged</p> <p>Validity: 3 years</p>
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5. SAFETY OF USE

5.1	<p>Technical safety:</p> <p>The technical precautions are described in the instructions NUP-MI.</p> <p>Be careful to attach safely the cannula to the syringe</p> <p>The MRI compatibility of our cannulas has not been tested</p> <p>The cannula is X-ray detectable</p>
5.2	<p>Biological safety:</p> <p>Be very careful to apply usual asepsis procedures</p> <p>Cannulas are made of stainless steel and nickel, allergic risk may be possible. In case of allergy, contact your doctor.</p>

6. INSTRUCTIONS FOR USE

6.1	<p>Manual:</p> <p>See NUP-MI</p>
6.2	<p>Indications:</p> <p>Aesthetic Group micro cannula is a single use medical device exclusively dedicated to the injection of filler under the skin</p>
6.3	<p>Using precautions:</p> <ul style="list-style-type: none"> - The product should not be reused. - Do not resterilize

- Entrusting the operation and use of the product and accessories only to persons with medical training, knowledge or experience required.
- Use the product only for the intended purpose, see Indications / Contraindications.
- Before each use, carry out a visual examination of the product to verify the integrity of the cannula before use: no loose, bent, broken, cracked and worn pieces.
- Never use a damaged or defective product. Set aside any damaged product.
- Check the integrity of the primary packaging before use. Never use this device when primary packaging is damaged.
- Do not use beyond the expiration date
- To attach the cannula to the syringe, grasp the cannula firmly by its plastic hub and:
 - For a simple male Luer syringe: push the Luer of the syringe as far as possible into the hub of the cannula.
 - For a syringe fitted with a male Luer Lock: push the cannula firmly into the end of the syringe while turning it clockwise.
- To remove it, grip the cannula in one hand, while rotating the syringe anticlockwise with the other hand. Gently remove the cannula.
- Use only with controlled delivery system as a syringe. The system is under the responsibility of the medical authority.
- Verify the integrity of the cannula upon removal

6.4

Contra-indications:

Do not exert excessive effort that can result in rupture of the cannula.

Do not use outside the hypodermis.

Do not use these cannulas for fat injection when the diameter is inferior to 21G.

It is advised that heavy smokers should stop smoking prior surgery. Smokers are advised to quit smoking at least a month before surgery. They must be cautioned for incidence of fluid collection.

7. ADDITIONAL PRODUCT INFORMATION

N/A

8. ANNEXES

N/A

9. PICTURES

