PRODIMED CATALOGUE **MEDICAL DEVICES**

PRODIMED



More than fifty years of experience in the development and manufacturing of medical devices have earned us the recognition of gynaecology and human reproduction specialists in France and throughout the world.

Prodimed is reaffirming its ongoing commitment to offer you better products and services:

Most of our products are manufactured in France, at our plant in Neuilly-en-Thelle (Oise, FRANCE).

This know-how has allowed us to keep expanding our product development into ever more technical and demanding areas, using materials of the highest medical quality.

Our mission is to offer to our customers the best in terms of quality, performance, reliability and value. Whether for our latest developments or for devices that have become international references, it is our constant desire to support changes in protocols developed by the best teams of clinicians and propose to them the best tools.

Our daily mission: to provide care to women and accompany them through each phase of their lives.

For more detailed information, please contact your local representative or:

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Prodimed sas

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Sterilization



Radiation

Radiation sterilization is used for all devices destined for Assisted Reproductive Technology (ART). STERILE R

Reproductive cells (sperm and eggs) or embryos are particularly sensitive to their environment, the Prodimed chose this technique to ensure that the sterilisation of the devices will have no impact on the survival and development of the cells.

Radiation sterilization consists in exposing the products to radiation. This technique ensures the complete absence of residual cytotoxic compounds, but may cause problems related to the degradation of certain materials.

For this reason, it cannot be used for all devices.

Ethylene oxide

Ethylene oxide (EO) is used for devices in contact with adult patients. STERILE EO

Products sterilised by EO must undergo an aeration cycle to eliminate gas residues. The quantity of residue is precisely controlled and must comply with international standards for acceptable dose limit.

French design and manufacturing





R&D teams are constantly developing innovative products to meet user needs.



The products are regularly inspected during the manufacturing process. For some products, inspection is carried out on 100% of them.









The plant manages all production techniques: extrusion, moulding and overmoulding.

Certifications

■ Certificates of conformity with requirements of international standards



ISO 13485: 2016 NF EN ISO 13485: 2016

■ CE certifications



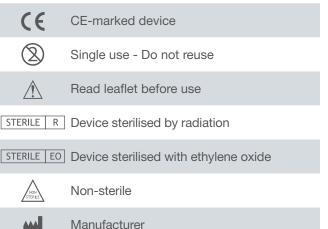
Devices for gynaecology and for medically assisted procreation Certificate n°20713; GMED n°38324



Vascular catheters and devices for medically assisted procreation Certificate n°20815; GMED n°38323

CE marking and symbols

Used on packaging





is damaged

Brands

The following brand names are registered and are the property of Prodimed:

HOC** OPS Pipelle TDT Echogyn* ART of PRODIMED Frydman

Size measurements

French gauge system

The gauge of instruments used was defined for the first time in 1849 by Charrière, a French manufacturer of surgical instruments. Used in the United States, the Charrière scale became the "French" system (F or Fr).

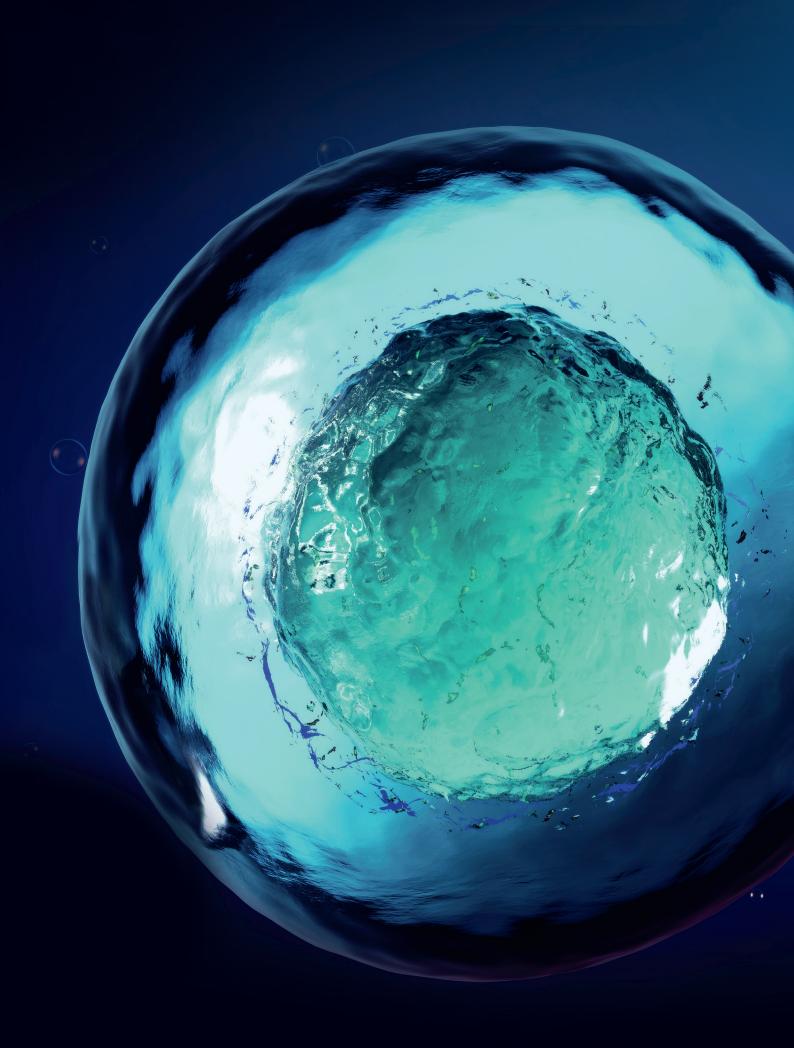
■ Charrière (Ch) or French (F/Fr) scale: 1 Ch = 1 F = 1/3 mm

Gauge

The gauge size of a needle indicates what the diameter of the lumen (opening) is. The higher the gauge, the smaller the diameter.

^{*} PATRICK CHOAY S.A (PCSA) property

^{**} PRODIMED property





ART

Assisted Reproductive Technology

For more than fifty years, Prodimed has been working in partnership with doctors and biologists to help couples who wish to have children.

From insemination catheters to embryo transfer catheters, and follicular puncture sets, Prodimed does its best to offer high-quality and innovative products in line with technical advancements and best practices.

Follicular puncture

OPS® ART of Prodimed sets STERILE R 2





Pre-connected sets for follicular puncture

Composition:

- Single-lumen, triple bevel and echogenic with engravings.
- Kink-resistant polyurethane tubes.
- Caps ensuring vials are leakproof during collection.

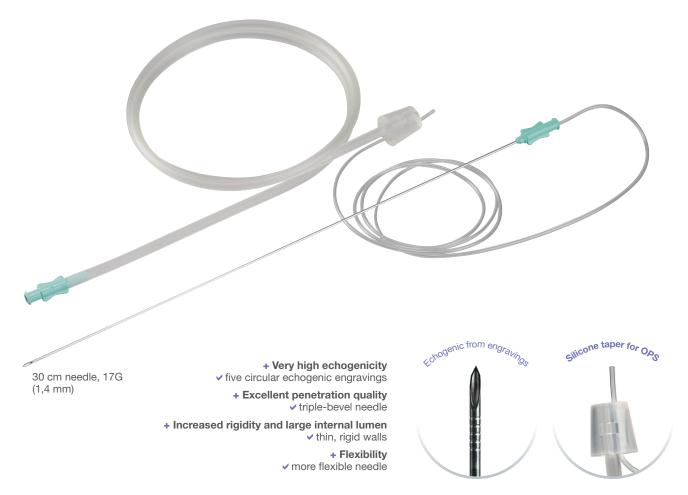
- The ART of Prodimed sets limit the risk of fracturing the zona pellucidan (follicular puncture using pump for better control of aspiration).
- ART needles for enhanced ultrasound monitoring and easier insertion into tissue.

Versions:

- OPS.
- With tap (the 3-way tap designed for rinsing and flushing the needle).



3-way tap



Product	Order	Internal	Тар		Needle		Aspi	iration tu	bing		Сар	Packaging
Name	Reference	Reference	Iap	Туре	Length	Diam.	Length	Ø Int.	Ø Ext.	Туре	Compatibility	rackayiiiy
OPS ART of Prodimed	1314100	7003845	Oui	ART**	30 cm	17G	100 cm	1,1 mm	2 mm	Silicone cone	15 ml vial type Falcon	10 /box

Class Ila medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.

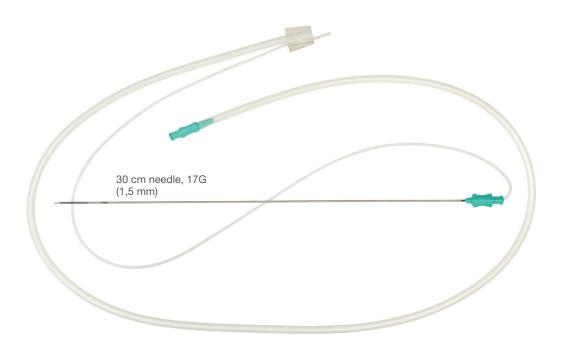


OPS® Classic sets STERILE R 2



Premium pre-connected sets for follicular puncture

- Composition:
 - Classic needle. Single-lumen, double-bevel and echogenic due to sandblasting.
 - Kink-resistant polyurethane tubes.
 - Caps ensuring vials are leakproof during collection.
- - The Classic sets limit the risk of fracturing the zona pellucida (follicular puncture using pump for better control of aspiration).
- Versions:
 - OPS.
 - Without tap.





+ Large internal lumen ✓ thin walls



Product	oduct Order Internal		Тар	Needle			Aspiration tubing				Сар	Packaging
Name	Reference	Reference	Iap	Туре	Length	Diam.	Length	Ø Int.	Ø Ext.	Туре	Compatibility	rackayiiiy
OPS	1311800	7003819	No	Classic	30 cm		60 am	1.1 mm	0	Silicone	15 ml vial	10 /box
Classic	1312100	7003822	No	(sandblasted tip)	35 cm	17 G	60 CIII	1.1 111111	2 111111	cone	type Falcon	IU/DOX

Class Ila medical device. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.

Follicular puncture

Ovo ART of Prodimed and Classic needle STERILE R (2)





Needles with advanced technology for egg retrieval

Ovo ART of Prodimed needle

- Composition:
 - Single-lumen, triple bevel needle, highly echogenic with engravings.
 - Luer-Lock tip.
- - High-quality steel facilitating handling and sliding.
 - Triple-bevel to easily penetrate tissue.
 - Very high echogenicity for better control.

Classic needle

- Composition:
 - Single-lumen, double-bevel needle, echogenic due to sandblasting.
 - Luer-Lock tip



Two needle versions

ART of Prodimed version

- + Very high echogenicity
- ✓ five circular echogenic engravings
- + Excellent penetration quality
- + Increased rigidity and large internal lumen
- √ thin, rigid walls
- + Flexibility
- ✓ more flexible needle

Classic version



- + High echogenicity
- ✓ sandblasted tip
- + High penetration quality
- ✓ double-bevel needle
- + Large internal lumen

Product Name	Order Reference	Internal Reference	Total length	ength Echogenicity		Needle Ext. Ø	Packaging
Ovo needle ART of Prodimed	1313700	7003843	30 cm	Engraving	1.0 mm	1.4 mm 17G	10 /box
Ovo Classic needle	1310100	7003805	25 cm	Sandblasting	1.2 mm	1.5 mm 17G	10 /box
Ovo Classic needle	1310200	7003807	30 cm	Sandblasting	1.2 mm	1.5 mm 17G	10 /box

Class IIa medical device. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.



Catheter 1 piece

Frydman® Classic STERILE R 2

The original catheter for embryo transfer, with flexible tip.





Product Name	Order Reference	Internal Reference	Туре	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
Frydman Classic 4.5	1320200	7003848	Straight	18 cm	1.6 mm	1.1 mm	No	25 /box
Frydman Classic 5.5	1320500	7003852	Straight	19 cm	1.6 mm	1.1 mm	No	25 /box

Frydman® Memory STERILE R 🕲





Basic malleable catheter



• The malleable catheter can be curved to adapts its shape according to the cervical profile, for insertion into very narrow or complex cervixes.





Product Name	Order Reference	Internal Reference	Туре	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
Frydman Memory	1320300	7003850	Malleable	18 cm	2.10 mm	1.1 mm	No	10 /box

Class I sterile medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.



Catheter 2 pieces

Echogyn® Embryoview M STERILE R 🕲







- Composition:
 - Supported, flexible catheter with echogenic insert at its end for ultrasound monitoring.
 - FEP (fluoroethylene propylene) insertion sheath for improved sliding.





Order	Ordor	Internal	Insertion sheath		Catheter				
Product Name	Reference	Reference	Useable length	Ø Ext.	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
Echogyn Embryoview M 18 cm	1325900	7003905	13 cm	2.3 mm	21 cm	1.57 mm	0.55 mm	Yes	10 /box

Class I sterile medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.



Catheter 2 pieces

Frydman® Ultrasoft STERILE R 2

2-pieces set for embryo transfer with ultra-flexible catheter

- Composition:
 - Ultra-flexible catheter
 - Catheter supported on its proximal end to facilitate handling.
 - Stylet sold separately to increase rigidity, curve and protect the insertion sheath during passage into the cervix.





_ Order	Ordor	Internal	Insertion sheath		Catheter				
Product Name	Reference	Reference	Useable length	Ø Ext.	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
Frydman Ultrasoft	1324100	7003882	18 cm	2.2 mm	21.5 cm	1.55 mm	0.7 mm	No	10 /box
Stylet for Frydman Soft Ultrasoft	1320700	7003854	18.8 cm	1.6 mm	N/A	N/A	N/A	N/A	10 /box

Frydman® Ultrasoft Echo STERILE R 2







2-pieces set for embryo transfer with ultra-flexible catheter and echogenic ring

- Composition:
 - Ultra-flexible catheter with echogenic ring at the tip for better control.
 - Catheter supported on its proximal end to facilitate handling.
 - Stylet sold separately to increase rigidity, curve and protect the insertion sheath during passage into the cervix.



	Order Reference	Internal Reference	Insertion sheath		Catheter				
Product Name			Useable length	Ø Ext.	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
Frydman Ultrasoft Echo	1324200	7003883	18 cm	2.2 mm	21.5 cm	1.55 mm	0.7 mm	Yes	10 /box
Stylet for Frydman Ultrasoft Echo	1320700	7003854	18.8 cm	1.60 mm	N/A	N/A	N/A	N/A	10 /box

Class I sterile medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged. Frydman Ultrasoft echo exist aslo in 3 pieces «Ultrasoft Frydman Set Echo With Guide. Product information in the next part 3 pieces catheters».

Catheter 3 pieces

Ultrasoft Frydman® Set with Guide





	Order	Internal	Insertion sheath		Catheter				
Product Name	Reference	Reference	Useable length	Ø Ext.	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
Ultrasoft Frydman® Set with Guide	1321600	7003862	14,5 cm	2.2 mm	22,5 cm	1.55 mm	0.7 mm	No	10 /box

Ultrasoft Frydman® Set Echo with Guide STERILE®





Order	Ordor	Internal	Insertion sheath		Catheter					
Product Name	Reference	Reference	Useable length	Ø Ext.	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging	
Ultrasoft Frydman® Set Echo with Guide	1322800	7003869	14,5 cm	2.2 mm	22,5 cm	1.55 mm	0.7 mm	Yes	10 /box	

Class I sterile medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.

TRODIMED TRODIMED



Frydman® Soft with stylet STERILE R 2







- Flexible catheter, supported at its proximal end to facilitate handling, offered with an insertion sheath equipped with an integrated stylet.
- Introduction sheath to facilitate passage through all cervical profiles.
- Malleable stylet to curve the introduction sheath.





Product Name	Order Reference	Internal Reference	Insertion sheath		Catheter				
			Useable length	Ø Ext.	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
Frydman Soft with stylet	1320900	7003857	14.5 cm	2.2 mm	22 cm	1.6 mm	1.15 mm	No	10 /box

Catheter 3 pieces









Ultra-thin transfer catheter

- Composition:
 - Ultra-thin transfer catheter, supported on its proximal end to facilitate handling.
 - Insertion sheath with flexible end and two insertion markers at 5.5 and 6.5 cm.
 - Malleable metal stylet coated with polyethylene to shape the insertion sheath and facilitate passage through the cervix.



Product Name	Order	Internal	Insertion sheath		Catheter				
	Reference	Reference	Useable length	Ø Ext.	Useable length	Ø Ext.	Ø Int.	Echogenic	Packaging
TDT Set	1322000	7003866	18 cm	2.2 mm	22.7 cm	1 mm	0.6 mm	No	10 /box

Class I sterile medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.

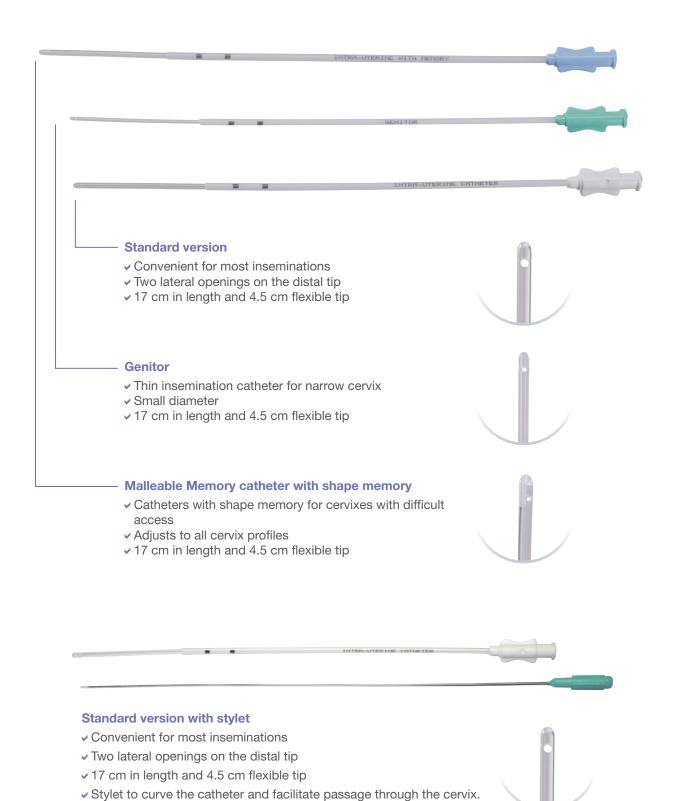
Intrauterine insemination

Intrauterine insemination catheters STERILE R (2)





A range of catheters adapted to different needs



Class I medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.

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Intrauterine insemination

A range of catheters adapted to different needs

Intrauterine insemination catheters

Product Name	Order Reference	Internal Reference	Useable length	Length flexible tip	Int. volume	Ø Int.	Ø Ext.	Packaging
Standard IUI	1221700	7003799	17.5 cm	4.5 cm	0.40 ml	1.65 mm	2.10 mm	25 /box
Genitor IUI	1220800	7003790	17.5 cm	4.5 cm	0,10 ml	0.70 mm	1.60 mm	25 /box
Malleable memory IUI catheter with shape memory	1221400	7003795	18 cm	4.5 cm	0.27 ml	1,10 mm	2.10 mm	25 /box
Standard IUI catheter with stylet	1221300	7003794	17.5 cm	4.5 cm	0.40 ml	1.65 mm	2.10 mm	25 /box

Class I medical devices except for transport model catheter: Class IIa medical device. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.



Functional exploration of the female reproductive system

Prodimed has long been regularly developing new devices in collaboration with doctors, to meet their needs and improve the quality of gynaecological exams.



P Endometrial biopsy







Endometrial biopsy by aspiration, for effective endometrial cancer screening

- The Pipelle is the gold standard for the screening of endometrial cancers, with more than two hundred publications attesting to its effectiveness, reliability and safety.
- Its aspirating force provides high-quality sampling.



Product Name	Order References	Internal References	Ø Ext.	Ø Int.	Length	Ø Lateral opening	Sampling type	Packaging
Pipelle	1111000	7003760	3.1 mm	2.6 mm	23.5 cm	2.1 mm	Histology	25 /box

Pipelle® Mark II STERILE EO 3







Histological and cytological sampling in one procedure

- The Pipelle Mark II, an improved version of the Pipelle, has a rough distal tip providing for the sampling of endometrial surface cells.
- For an even more thorough sample collection, allowing for histology and cytology in just one procedure.



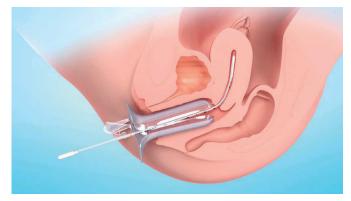


Product Name	Order References	Internal References	Ø Ext.	Ø Int.	Length	Ø Lateral opening	Sampling type	Packaging
Pipelle Mark II	1111200	7003762	3.1 mm	2.6 mm	23.5 cm	2.1 mm	Histology + cytology	25 /box

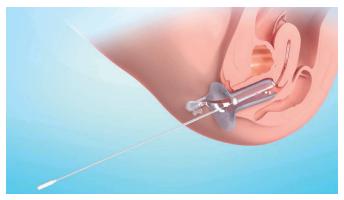
Class I sterile medical devices. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.

Endometrial biopsy

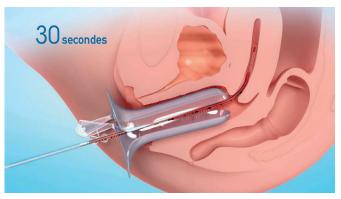
Easy to use



1- Insert the Pipelle® until reaching the uterine fundus



2- In one movement, pull on the plunger to bring it as far as it will go



3- Sweep the uterus for 30 seconds, in back-and-forth movements and rotations



4- Cut the tip of the Pipelle®



5- Push the plunger back in again to empty the content

Class II medical device according the US FDA regulation. Manufacturer: Prodimed - CE0459. Carefully read the instructions on the labelling. Use before the expiry date indicated on the wrapping. Do not use if the wrapping or primary packaging is damaged.

Note



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