

1. Product Name and Product Code:

Postpartum Balloon / 05TD0206

2. Intended Use:

Postpartum Balloon is a disposable, multiple lumen catheter attached to an inflatable balloon system designed to provide tamponade for controlling hemorrhage from the uterus and vagina. Postpartum Balloons meet the BS EN ISO 20696:2018 Sterile urethral catheters for single use standard. Postpartum Balloon does not include Latex and Phthalate.

3. Product Description:



3.1. Classification:

Class-IIa

3.2. Raw Material List:

- Catheter
- Balloon
- Luer Lock Connector
- 3 Way Stopcock
- One Way Check Valve
- Serum bag spike
- 50ml Injector

Table 3.2.1. Postpartum Balloon Part List

Reference Number of Main Product	Reference Number of Product Parts	Product part Name	Raw Material
05TD0206	05TD0088	Postpartum Balloon and Catheter	Medical Grade Silicon
	05TD0087	Luer Lock Connector	ABS
	05TD0179	3 Way Stopcock	Polycarbonate
	05TD0180	One Way Check Valve	Polycarbonate
	05TD0114	Serum Bag Spike	Low Density Polyethylene
	05TD0115	50ml Injector	Polypropylene

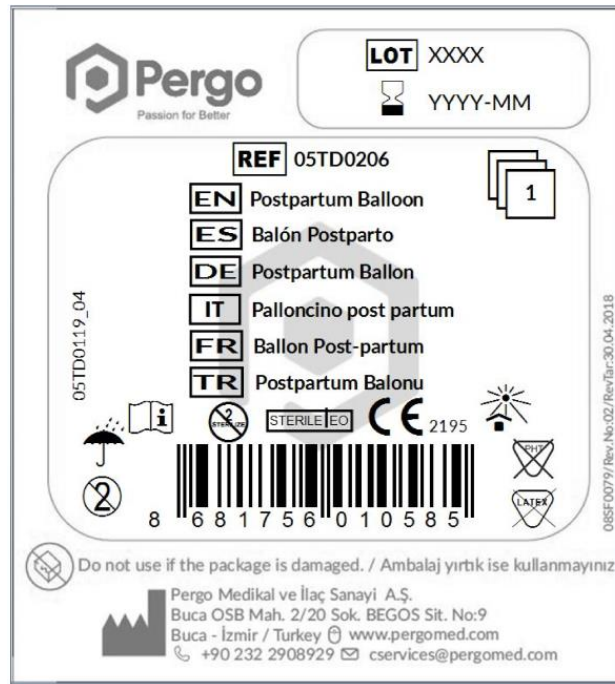
Table 3.2.2. Postpartum Balloon Technical Specifications

Spec	Unit	Value
Diameter (Tube)	Fr	24
Color	-	Transparent
Catheter Length	mm	587 ±6
Inflation Volume	ml	≤500
Wall Thickness (Balloon)	mm	0,7 ± 0,1

4. **Sterilization Method:**
 Sterilization by ethylene oxide.

5. Packing:**5.1. Primary Package:**

Postpartum Balloon is placed in a PE inner pouch. And the inner pouch is placed in sterile pouch.

5.1.1. Primary Package Label:**5.2. Secondary Package:**

A Postpartum Balloon which is placed in the sterile pouch is placed in 375x255x40 mm cartoon box.

5.2.1. Secondary Package Label:**5.3. Tertiary Package:**

10 pcs inner boxes are placed in a 300x400x450 mm case.

5.3.1. Tertiary Package Label:



6. Applied Standards:

- TS EN 1616
- TS EN 1618
- TS EN ISO 80369-7
- ISO 8536-10
- ASTM F88-05
- TS EN ISO 13485:2016
- TS EN ISO 14971:2013
- TS EN 1041
- ISO 15223-1:2016
- TS EN ISO 10993-1:2011
- ASTM F1980-02

7. Storage:

All Pergo products should be stored in a closed and warm environment. All products should be protected from damp, dirty and dusty environments. Product is not disposable.

8. Shelf Life:

3 years from production date.

9. Cleaning and Disposal:

Pergo Postpartum Balloons are sterile and single use. The products to be destroyed should be disposed of in accordance with hospital disposal policy.

Change Control Log:

Revision#	Revision Date	Revised Sections	Description of the Version	Affected Documents
00	04.02.2022	N/A	First Issue	N/A
The latest revision of the document is available on company server "Pergo QMS". The printed copies are <i>NOT CONTROLLED</i> unless they have a red "CONTROLLED DOCUMENT" stamp		Prepared by Kadir GEZER Engineering Design Officer	Reviewed by Orcan KAYA Product Group Leader	Approved by Ozan BARAN General Manager

Distributed to:

Name Surname	Title	Signature	Date	Revision No