

Title: Tumark® Patient Leaflet and Implant Card**Patient Implant Card**

Tumark® Biopsy Markers

Product Number:	
Lot Number:	
UDI:	
Patient Name:	
Patient Identification Number:	
Left or Right Breast:	
Doctor:	
Hospital or Clinic:	
Date:	



SOMATEX Medical Technologies GmbH
Hohenzollerndamm 150/151, 14199 Berlin, GERMANY

Hologic.com

Australian Sponsor

Hologic (Australia and New Zealand) Pty Ltd
PO Box 1971 Macquarie Centre NSW 2113

Email: australia@hologic.com
Tel: 1800 264 073

Title: Tumark® Patient Leaflet and Implant Card

Patient Information Leaflet

Product Number	Description	UDI
271510	Tumark Eye 18 G / 1.20 x 100 mm	04250195611352
271512	Tumark Eye 18 G / 1.20 x 120 mm	04250195611376
271548	Tumark Professional Q-Shape 18 G / 1,20 x 100 mm	04250195607089
271549	Tumark Professional X-Shape 18 G / 1,20 x 100 mm	04250195607096
271551	Tumark Professional X-Shape 18 G / 1,20 x 120 mm	04250195607102
271555	Tumark Professional Q-Shape 18 G / 1,20 x 120 mm	04250195611116
271559	Tumark Professional 18 G / 1.20 x 100 mm	04250195607119
271560	Tumark Professional 18 G / 1.20 x 120 mm	04250195604637
271589	Tumark Vision 10cm	04250195611093
271590	Tumark Vision 12cm	04250195607843
271660	TULOC 20 G / 0.95 x 50 mm	04250195604705
271661	TULOC 20 G / 0.95 x 90 mm	04250195604712
271663	TULOC 20G / 0.95x120mm	04250195604729
271770	DUO system PREMIUM 20 G / 0.95 x 50 mm	04250195604736
271771	DUO system PREMIUM 20 G / 0.95 x 90 mm	04250195604743
271773	DUO system PREMIUM 20 G / 0.95 x 120 mm	04250195604750
271880	TULOC PREMIUM 20 G / 0.95 x 50 mm	04250195604767
271881	TULOC PREMIUM 20 G / 0.95 x 90 mm	04250195604774
271883	TULOC PREMIUM 20G / 0.95 x 120 mm	04250195604781
Tumark-BREV-P-Q	Tumark Professional Q for Brevera Petite	14250195611335
Tumark-BREV-P-Vision	Tumark Vision for Brevera Petite	14250195611298
Tumark-BREV-P-X	Tumark Professional X for Brevera Petite	14250195611311
Tumark-BREV-S-Q	Tumark Professional Q for Brevera Standard	14250195611328
Tumark-BREV-S-Vision	Tumark Vision for Brevera Standard	14250195611281
Tumark-BREV-S-X	Tumark Professional X for Brevera Standard	14250195611304
Tumark-E13-P-Q	Tumark Professional Q for Eviva Petite	14250195611274
Tumark-E13-P-Vision	Tumark Vision for Eviva Petite	14250195611236
Tumark-E13-P-X	Tumark Professional X for Eviva Petite	14250195611250
Tumark-E13-S-Q	Tumark Professional Q for Eviva Standard	14250195611267
Tumark-E13-S-Vision	Tumark Vision for Eviva Standard	14250195611229
Tumark-E13-S-X	Tumark Professional X for Eviva Standard	14250195611243

Title: Tumark® Patient Leaflet and Implant Card**Intended Purpose**

Intended to attach a marker to soft tissue at the surgical site during a percutaneous procedure. The devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following a percutaneous procedure. They are not indicated to be used with magnetic resonance imaging (MRI) techniques

Instructions For Use

Only qualified physicians with knowledge, experience and training in percutaneous soft tissue marking should use the product.

Intended Performance and Side Effects

Intended to attach a marker to soft tissue at the surgical site during a percutaneous procedure. The devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following a percutaneous procedure. They are not indicated to be used with magnetic resonance imaging (MRI) techniques.

The use of the products is contraindicated in patients who suffer from a severe nickel allergy.

Residual Risks

The risks associated with these devices have been reduced to an acceptable level and are adequately described in the labeling.

Interaction of the Device with Other Equipment

- The marker application system is NOT suitable for deployment under MRI.
- DO NOT use the system in patients with breast implants.

Post Implantation

- Biopsy Site Markers are implanted sterile, they serve no other function but as a Marker, there are no preventative examination or monitoring required.
- Biopsy Site Markers are permanent implants that do not have end of life, no near end of life precaution or action is required.

Materials and Substances

Non-absorbable nickel-titanium (Nitinol).

Reporting of Incidents

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration at <https://www.tga.gov.au/reporting-problems>.



SOMATEX Medical Technologies GmbH
Hohenzollerndamm 150/151, 14199 Berlin, GERMANY

Hologic.com

Australian Sponsor

Hologic (Australia and New Zealand) Pty Ltd
PO Box 1971 Macquarie Centre NSW 2113

Email: Australia@hologic.com
Tel: 1800 264 073

Title: Tumark® Patient Leaflet and Implant Card

Reference IFUs:

- 999835 GA Tumark Eye
- 999873 GA Tumark Professional
- 999834 GA Tumark Vision
- 999877 GA Tuloc Premium
- 999869 GA Tuloc
- 999872 GA Duo System Premium
- 999823 GA-Hologic Tumark Professional Q for Eviva&Brevera
- 999824 GA-Hologic Tumark Professional X for Eviva&Brevera
- 999822 GA-Hologic Tumark Vision for Eviva&Brevera