**EVALUATION FORM**

To be completed at each routinely performed control within a year after first insertion of the plugs

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**PATIENT**

Centre number (CIC) ………………..                  Unique Identification Code (UIC):          ............................

Hospital Unique Patient Number: ..............................

Initials: ..............................(first name(s)-surname(s))

Type of punctal plugs inserted

- [ ] Silicone Punctal Plugs
- [ ] SmartPlugs

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**DATE of VISIT**

Date punctal plugs were installed ..............................

Date of visit ..............................

Number of visit since punctal plugs were installed:

- [ ] First
- [ ] Second
- [ ] Third

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**Condition of the Eyes at time of visit**

**SYMPTOMS:**

**Distinctive**

- [ ] New onset of dry eyes
- [ ] Gritty eyes
- [ ] Painful eyes
- [ ] Cicatricial conjunctivitis
- [ ] Keratoconjunctivitis sicca or confluent areas of punctuate keratopathy

**Other features**

- [ ] Photophobia
- [ ] Periorbital hyperpigmentation
- [ ] Blepharitis (erythema of the eyelids with erythema)
- [ ] Other (specify) …………………………………………………………………………...
EBMT/CLWP and LEWP – Non-interventional Prospective Study on punctal occlusion for the treatment of dry eyes after allo-tx  
Study number: 42207729

CIC: ………… Unique Patient Number (UPN): ……………………… SCT Date: ……… …….. …………

Evaluation/Follow up: Please send form to: Anja Henseler, CLWP Data Office

FORM (version 01-03-2010)

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Subjective Parameters

Eye Symptoms Score:

- Score 0: no symptoms
- Score 1: mild dry eye symptoms not affecting ADL (requiring eye drops ≤ 3 x per day) OR asymptomatic signs of sicca keratitis
- Score 2: Moderate dry eye symptoms partially affecting ADL (requiring drops > 3 x per day or punctal plugs, WITHOUT vision impairment)
- Score 3: Severe dry eyes symptoms significantly affecting ADL (special eyeware to relieve pain) OR unable to work because ocular symptoms OR loss of vision caused by pseudomembranes or corneal ulceration

Use of daily topical lubricant(s) medication (diminished use should not have resulted in worsening of symptoms)

Name of the topical lubricant:

Frequency of use:
- Not on a daily basis
- 1-3 times a day
- 4-6 times a day
- > 6 times a day

Objective Tear Dynamic Parameters

Schirmer’s tear test (According to NIH Consensus, done without anesthesia)

Mean score on Schirmer’s test: □ > 10 mm
EBMT/CLWP and LEWP – Non-interventional Prospective Study on punctal occlusion for the treatment of dry eyes after allo-tx

study number 42207729

CIC: …………… Unique Patient Number (UPN): ……………………… SCT Date ......... - ........ - ........  

dd      mm      yyyy

Evaluation/Follow up Please send form to:

Anja Henseler, CLWP Data Office
Dept. Medical Statistics, LUMC, Postzone S-5-P
P.O. Box 9600
NL-2300 RC Leiden
The Netherlands

FORM (version 01-03-2010)

Please send form to:

Anja Henseler, CLWP Data Office
Dept. Medical Statistics, LUMC, Postzone S-5-P
P.O. Box 9600
NL-2300 RC Leiden
The Netherlands

or fax: +49-180-500-290-623
or +49-711-4900-872
or e-mail: clwpebmt@lumc.nl

Objective Corneal Damage Parameter

Standard fluorescent punctate staining, scored according to “The National Eye Institute Corneal Grading System”:

Each cornea is divided in five areas. Each area is scored for fluorescent staining (0 = absent, 1 = present; >3 is abnormal).

Fluorescent score OD:  

Fluorescent Score OS:

Area 1: I I  
Area 2: I I  
Area 3: I I  
Area 4: I I  
Area 5: I I  

Area 1: I I  
Area 2: I I  
Area 3: I I  
Area 4: I I  
Area 5: I I  

Tear Film Break-up Time

☐ 6 – 10 mm  
☐ ≤ 5 mm

☐ < 5 sec  
☐ 5 – 10 sec  
☐ 10 – 15 sec  
☐ > 15 sec
Complications of punctal plug insertion

Loss will not be judged as complication or failure in case of prompt replacement; need for placement in upper nasolacrimal canaliculi is also not judged as complication or failure.

**COMPLICATIONS OCCURING AFTER THE INSERTION OF PUNCTAL PLUGS**

- Ocular discomfort
- Ocular irritation
- Spontaneous loss without prompt replacement
- Granulomas
- Canalicular migration with secondary nasolacrimal obstruction
- Canaliculitis
- Dacryocystitis requiring surgical removal

Date complications first occurred

- dd
- mm
- yyyy

**Documentation of alternative treatment after punctal plug installation**

**REASON FOR THE USE OF ALTERNATIVE TREATMENT**

- Repeated loss
- Complication(s)
- No effect of punctal plugs
- Other reason (specify) …………………………………………………………………………

**TYPE OF ALTERNATIVE TREATMENT**

- Topical lubricant (specify) …………………………………………………………………………
- Other type of punctal plug
- Other (specify) …………………………………………………………………………

Date alternative treatment was started

- dd
- mm
- yyyy